

# **Use of Mobile Devices and the Internet to Streamline an Asthma Clinical Trial (MICT)**

## **Manual of Procedures** Version 1.0

WORKING DOCUMENT  
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# 1. Study Overview

## 1.1. Design and Outcome Methods

### Objective

To test the hypothesis that incorporation of mobile devices and the internet into a study design that tests interventions to reduce morbidity in pediatric asthma will result in a lower-cost method for conducting a clinical trial and encourage more families to participate. We will test two novel features in a streamlined clinical trial design. Results will be compared with a currently funded traditional clinical trial (Long-acting Beta Agonist Step Down Study (LASST) conducted by the American Lung Association Asthma Clinical Research Centers (ALA-ACRC) network.

### Study Design

- **Trial Type Comparison**
  - MICT vs. LASST (60 participants in MICT and 60 in LASST)
- **Treatment Comparison**
  - Continuation of Fluticasone/Salmeterol Diskus 250/50 mcg twice daily
  - Reduced dose Fluticasone/Salmeterol Diskus 100/50 mcg twice daily
  - Fluticasone Diskus alone 250 mcg twice daily without Salmeterol

### Primary Outcome

Difference in Research Participation Assessment interview score for parental permission and assent at screening and at 12 weeks after randomization in parents and youths participating in the MICT (*streamlined*) trial compared with the LASST (*traditional*) trial

### Secondary Outcomes

- The timeliness and completion rates of study data entered online by participants at home into REDCap in MICT compared with data completion using paper forms in LASST.
- The quality of spirometry performed by children at home using the Easy One Plus and real FaceTime video coaching in MICT using the iPad2/3G compared with the quality traditional spirometry performed with coaching in the clinic setting in LASST
- Differences in ACT scores for participants in MICT compared with ACT scores for participants in LASST

## 1.2. Eligibility Criteria

Participants whose asthma is well controlled on a moderate dose of combination ICS and LABA therapy. Asthma control will be determined by Asthma Control Test Scores, history of asthma symptoms and medication, as well as lung function.

### 1.2.1. Study Eligibility

#### 1.2.1.1. Inclusion Criteria for Open-Label Stable Phase

Gender and Age:

- Males and females, age 12 years or older

Asthma Treatment:

- Physician diagnosed asthma that is well controlled on:
  - Fluticasone/Salmeterol Diskus – 250/50 mcg, 1 puff 2x daily
  - Fluticasone/Salmeterol HFA – 115/21 mcg, 2 puffs 2x daily
  - Budesonide/Formoterol – 160/4.5 mcg, 2 puffs 2x daily
  - Mometasone/Formoterol – 100/5 mcg, 2 puffs 2x daily

Or a combination of moderate dose ICS + long-acting beta agonist:

Moderate dose ICS (total daily dose)

- Fluticasone/Salmeterol Diskus – 250/50 mcg, 1 puff 2x daily
- Fluticasone HFA – greater than 264 mcg and up to 480 mcg/day
- Fluticasone Diskus – greater than 300 mcg and up to 500 mcg/day
- Mometasone – 400 mcg/day
- Beclomethasone – greater than 240 mcg and up to 480 mcg/day
- Ciclesonide – 320 mcg/day
- Budesonide – greater than 600 mcg and up to 1200 mcg/day

Long-acting beta agonist

- Salmeterol Diskus – 50 mcg every 12 hours
- Formoterol – 12 mcg every 12 hours

Asthma Control Test (ACT) score greater than or equal to 20

Hospitalizations for Asthma: no more than one hospitalization in the 9 months prior to enrollment

In the 4 weeks prior to enrollment:

- No unscheduled doctor/ED/hospital visits for asthma
- No use of rescue prednisone (oral or IV)

Pre-BD FEV<sub>1</sub> greater than or equal to 70% predicted

Females of childbearing potential: not pregnant, not lactating and agree to practice an adequate birth control method (abstinence, combination barrier and spermicide, or hormonal) for the duration of the study

Smoking

- Less than 10 pack-year history of tobacco use

And:

- Abstinence from smoking for more than 1 year

Other

- Parent/Guardian and Participant must speak English

**1.2.1.2. Exclusion Criteria for Open-Label Phase**

Poor asthma control:

- Near fatal asthma (intubation or ICU admission for asthma) within 2 years of enrollment
- High risk of near fatal or fatal asthma as defined by one or more of the following criteria:
  - More than 2 hospitalizations for asthma in the previous year
  - More than 3 ED visits for asthma in previous year
  - Hospitalization for asthma in past month
  - Use of more than 2 canisters of inhaled short-acting beta2-agonist in past month
- Hospitalization or urgent care visit within 4 weeks of Visit 1.

Smoking:

- History of extensive environmental tobacco exposure per judgment of investigator

Other major chronic illnesses:

- Conditions which in the judgment of the Study Physician would interfere with participation in the study e.g. including but not limited to uncontrolled diabetes, uncontrolled HIV infection or other immune system disorder, hyperthyroidism, seizure disorders, renal failure, liver disease, non-skin cancer, unstable psychiatric illness
- Recent active substance abuse (in past 6 months)

- Lung disease other than asthma including COPD, bronchiectasis, sarcoidosis or other lung disease
- History of known premature birth less than 33 weeks or any significant level of respiratory care including prolonged O<sub>2</sub> administration or mechanical ventilation during the neonatal period
- Unstable cardiac disease (decompensated CHF, unstable angina, recent MI, atrial fibrillation, supraventricular or ventricular tachycardia, congenital heart disease, or severe uncontrolled hypertension)

Medication use:

- Chronic oral steroid therapy
- Xolair (Omalizumab) therapy in the previous 6 months
- Tiotropium (Spiriva)

“Drug” allergy:

- Drug allergies to any component of study drug or history of adverse reaction to short or long acting beta agonists

Participation in clinical trial:

- Participation in another clinical trial within the past 30 days

### 1.2.2. Randomization Eligibility

Continues to meet all eligibility criteria for enrollment

Successful completion of the fluticasone/salmeterol stable phase:

No unscheduled visits, no ED visits, and no hospitalizations for asthma

No change in asthma medication for entire 8 week stable phase period

Rescue beta-agonist use less than 2.3 puffs per day average (less than 16 puffs per week, excluding use as a pre-medication for exercise). One nebulizer use is equivalent to 2 puffs of beta-agonist

ACT score greater than or equal to 20 at V1, V2 and V3

Pre-BD FEV<sub>1</sub> greater than or equal to 70% predicted

Demonstrated adherence:

- Completed at least 10 days of the last 14 days of diary card entries
- Received treatment with Fluticasone/Salmeterol 250/50 for at least 21 days of the last 28 days (treatment = at least one dose for the day)

### 1.3. Study Visit Time Windows and Data Collection Schedule

Visit	V0	V1 Part 1	V1 Part 2	V2	V3	V4	V5	V6 Part 1	V6 Part 2
Time Window (weeks)		-12 to -10	-10 to -6	-6 to -2		2-4	5-7	11-13	
Target (week)		-11	-8	-4	0	3	6	12	
Type of visit <sup>1</sup>	Pre V1 Eligibility	Phone	Clinic	iPad/ FaceTime	iPad FaceTime	iPad FaceTime	iPad FaceTime	iPad FaceTime	Clinic
Trial Randomization	x								
Consent		x							

Eligibility evaluation <sup>2</sup>	x	x	x		x				
Pregnancy test			x						
Blood (DNA, allergy)									x
Height and Weight <sup>3</sup>			x	✓	✓		✓	✓	x
Vital Signs			x						x
Physical Exam			x						x
Treatment Randomization <sup>5</sup>					x				
RPA		x						x	
Screening Form		✓			✓				
Baseline asthma and medical history			✓						
ACT			✓	✓	✓	✓	✓	✓	
CHSA-Child			✓		✓		✓	✓	
Clinic Visit Form				✓	✓	✓	✓	✓	
EQ-5D			✓					✓	
QOL <sup>7</sup>			✓		✓		✓	✓	
Complete Morning and Evening reports on iPad				✓	✓	✓	✓	✓	
eNO			x						x
Spirometry Pre and Post <sup>6</sup>			✓	✓	✓	✓	✓	✓	
Treatment medication distribution <sup>4</sup>			x	✓	✓	✓	✓	✓	x
iPad Daily Report/PEF/AAP review			✓	✓	✓	✓	✓	✓	
Receive/Return iPad and EasyOne <sup>8</sup>			x						x

✓ Tasks completed by participants prior to FaceTime or Clinic Visit

**Minimum of one week required between each visit after V3**

(AAP) Asthma Action Plan  
 (ACT) Asthma Control Test  
 (CHSA) Children's Health Survey for Asthma-Child version  
 (eNO) Exhaled Nitric Oxide  
 (EQ-5D) EQ-5D 5 level  
 (RPA) Research Participant Assessment  
 (PEF) Peak Expiratory Flow  
 (QOL) Quality of Life

AE and Adherence monitoring done continuously via REDCap and email alerts.

1. Visit 1 (Part 1) and Visit 6 (Beginning of Part 1) are conducted via WebEx. Visit 6 (end of Part 1) will be conducted as a virtual visit. Visit 1 (Part 2) and Visit 6 (part 2) will be conducted in the clinic. Other visits are virtual visits.
2. Participants who do not qualify for treatment randomization will be required to come to the clinic at Visit 3 to return the iPad2/3G and EasyOne<sup>TM</sup> Plus spirometer.
3. Height and weight at V1 Part 2. Height only at V2, V3, V5 and V6. Will not check height at V4 due to short time between V3 and V4.
4. Study treatments provided to the participant other than open-label Advair and Proair dispensed at Visit 1 will be mailed via FedEx . Participant will return all study drug at Clinic V 6.



Current unexpired discus with remaining doses will be re-distributed to the participant.

Participant will receive Rx for one month supply of Advair or Flovent depending on which drug they received at randomization

5. Participants who qualify for randomization will be mailed study treatment to their home and instructed on use via FaceTime through the iPad2/3G during Visit 3.
6. After instruction at Visit 1, spirometry will be performed daily and 3 PEF values will be recorded on the Morning Report. Pre- and post- bronchodilator spirometry will be performed during virtual visits V2, V3, V5, and V6..
7. Quality of Life Questionnaires for participants  $\geq$  15 years old at time of enrollment . The system is programmed to send the questionnaire to this age group only.
8. Participant returns EasyOne at Clinic Visit 6. Participant returns iPad which will be cleared of study information and returned to participant.

## 2. REDCap Overview, Training, and Use

### 2.1. Overview

#### What is REDCap

- Nemours Bioinformatics Core facility (BCF) manages the Nemours installation of REDCap™ (Research Electronic Data Capture from the REDCap Consortium). REDCap is a secure web application that allows users to build and manage online surveys and databases for a variety of purposes including basic, clinical, translational and behavioral research, repositories and operational support. In addition to maintaining this application, BCF provides training and other support so that Nemours associates can utilize all the tools this resource provides

#### Reasons for Using REDCap for Study Staff and Participant Data Collection in MICT

- Accessibility – all study personnel can get to the data and do data entry from anywhere.
- Security - Data is stored on our servers, backed up nightly. Users must authenticate to view it. Users can be assigned different levels of permission such as read-only, add/edit data, delete records, etc. Users can also be restricted from viewing certain forms and exporting certain fields.
- Versatility - Data or data subsets can be easily selected, sorted, and exported in formats directly ready for analysis in SPSS, SAS, S+/R, or even Excel. Schedules can be automatically generated from defined events.
- Validity - Using a tool like REDCap to set up a database and data entry forms for a study is a valuable first step in being sure that you have covered all the devilish details that are inherent in designing a valid research study. The bioinformatics staff have expertise in database design and biostatistics and can help assure that your study is well thought out and implemented.

To learn more about REDCap, send us an [email](#), or visit the [REDCap Training Resources](#) page. (Note that you do not need to log into REDCap to view the tutorial videos).

### 2.2. How to get Access to REDCap

Nemours Bioinformatics Core facility (BCF) manages the Nemours installation of REDCap™. Access is obtained by going to the website on the link below and completing the online form AND the PDF form that must be signed that is also on this page (scroll to the bottom).

[http://www.nemoursresearch.org/snap/admin\\_forms/redcapacct.php](http://www.nemoursresearch.org/snap/admin_forms/redcapacct.php)

### 2.3. Training

Training is provided by Nemours Bioinformatics Core facility by Suzanne McCahan, PhD.

### 2.4. MICT REDCap Testing and Real Databases

#### Definition

- Two parallel data systems are used.
  - Test projects (begin with “test-MICT” as the name.
    - Allows study team members and the bioinformatics team to test and troubleshoot forms before they are used to collect actual study data
    - allows new staff to experiment with test participants to see how the data are collected and can be viewed
  - Live projects (begin with “MICT” as the name

## Organization

- Navigation of the REDCap database occurs using the tabs on the left
  - “My Projects” takes you to all the MICT training and live databases
  - “Data Collection” allows you to select a participant by going to “Add / Edit Records”
  - “Applications” probably won’t be used much by study staff
  - “Project Bookmarks”
    - Bookmarks that begin with “MICT…” allow for a one-click way to open a different MICT project
    - Bookmarks that do not begin with “MICT…” allow you to access specific participant information
      - If a User Name and Password are required:
        - User Name is your Nemours login name
        - Password is MICTstudy2013
  - “Reports” have been created to provide specific information the coordinators have requested

## 2.5. Demonstration Study Websites

### 2.5.1. Study Consent Website

#### Overview

- The study consent website houses the consent video and sidebar information in the video.  
(Click here to go to the document: [Sidebar Material.](#))

#### Viewing the Consent Website

- Study staff can view the video at <https://www.nemoursresearch.org/mict/>
  - User Name: preconsent
  - Password: pass

#### Participant Viewing

- Links to the study consent website are individualized for each participant
- The individual links allows the study staff to track viewing of the consent website by potential participants
- All data from viewing the website is stored in REDCap

### 2.5.2. Morning and Evening Reports Website – Demo Sites

#### Overview

- The website houses the Morning and Evening Reports
- Participants enter data on this website twice daily

#### Viewing the Demo Reports Website

- Study staff can view the Morning and Evening Reports website at <https://www.nemoursresearch.org/mict/>
  - User Name: postconsent
  - Password: pass

#### Participant Data Entry

- The Reports website is accessed by participants using unique user names and passwords
- All data from the website is stored in REDCap
- The individual links allows the study staff to track viewing of the consent website by potential participants

## 2.6. Participant ID vs. Username vs. Study Email Name

### Participant ID

- The Participant ID is generated during the recruitment process by the study recruiter in Jacksonville
  - The ID begins with the 3 letters indicating the study site (JAX, ORL, PNS, PHL, STL, WIL) followed by a 3 digit number beginning with 101 (JAX101)
  - The participant ID is used in REDCap to select your participant in “Add/Edit Records” and all REDCap forms and reports

### Username

- The username is generated by Bioinformatics sequentially
  - The user name is in the format of:
    - Study acronym “mict”
    - Study location “j”, “o”, “w”, “p”, “ph”
    - Sequential number starting with “101”
    - Example: “mictj101”
  - The user name is also the first part of the gmail email address
  - The user name is also the iPad ID

### Study Gmail Email and Apple ID and Passwords

- A gmail study email account is created for each participant by Nemours IT (example: [mictj101@gmail.com](mailto:mictj101@gmail.com))
  - The gmail address is used as the Apple ID
- The **initial password** for the gmail account and Apple account is based upon the 3 digits in the user name + 1234 and the study site initial
  - If the username is mictj101, the initial password for the gmail account and Apple account is “1335mictJ” – upper and lower case are important
  - If the participant changes their password, we are unable to tell them what it is
    - They will need to reset their password if they cannot remember it
      - This is done within gmail

### iPad Passcode

- The iPad is set up to have a 4-digit passcode in order to use the iPad.
- The 4-digit iPad passcode is the sum of the 3 digits in the user name + 1234 (e.g for the participant who is JAX101, the iPad passcode is 101+1234=1335)

### Gmail Recovery Email

- The participant may be asked to put in a recovery email in order to access their study gmail account
- The gmail recovery email is: [mictsupport@nemoursresearch.org](mailto:mictsupport@nemoursresearch.org)

### Finding Participant ID, Username, and Initial Passwords in REDCap

- Go to the MICT-web info REDCap project
  - Go to the “Data Search” section
    - In “Choose a field to search”, put in the participant ID (this is usually the easiest piece of data that you remember about your participant)
    - In “Basics”, you will find the Initial Password and the Participant ID
    - In “Password”, you will find the Username

### Providing Participants with their Participant ID, Username, and Initial Passwords

- When the SC receives the iPad from JAX, inside the box will be a form that includes the Participant ID, Username, and Initial Passwords. A completed copy of this form can be found in the folder for your site. (**Click here to go to the blank form: [User name Passwords Gmail AppleID.docx](#)**)
  - In this folder (**Click here to go to the folder: [User Name Password Form](#)**), you will see folders for each site. The AC will have the participant form saved in the folder for your site. The SC can print extra copies of the form if needed.







## 2.7. Editing Data in REDCap

### Overview


- REDCap tracks all editing done on the participant's record. The edited data will identify the person logged into REDCap and the date and time of the edits.

### How to Make Edits in REDCap

Example: You need to edit the Evening Report entry. The participant indicated they "used oral or IV prednisone/steroids for asthma" but according to a conversation you had with the family they have not used steroids. You will want to contact the family when you see alerts that should be investigated with the family. Go to the record that needs editing.

Used oral or IV prednisone/steroids for asthma	 <input checked="" type="radio"/> Yes  <input type="radio"/> No
Used inhaled corticosteroid other than study diskus for asthma	 <input type="radio"/> Yes  <input checked="" type="radio"/> No
<b>New or increased dose of asthma medicine</b> - Do NOT include: (a) the use of study diskus (already listed above) rescue medications (already listed above) (b) oral or IV prednisone/steroids for asthma (already listed above) (c) inhaled corticosteroids other than study diskus (already listed above)	
	 <input type="radio"/> Yes  <input checked="" type="radio"/> No

Click on the little balloon next to "Used oral or IV prednisone/steroids for asthma". Change the data to the correct entry. Enter your comment. There is no need to put your name or date/time as REDCap will have this. Click on "Comment" to save your comment.


**Field Comment Log**


This pop-up displays all the field comments for the record and field specified below. Users with access to data entry forms may leave one or more comments on any field on a data collection instrument, after which the balloon icon will stay lit up to signify that comments exist for that field for this record. All field comments for all records/fields can also be viewed, keyword searched, and filtered on the [Field Comment Log](#) page in this project. NOTE: If you wish to prevent all users in this project from editing or deleting field comments below, see the Additional Customizations popup on the Project Setup page.

Record This is the primary key for this project. It is created using the participant ID and date for the submission: [2\\_2013-07-25](#)

Field: **dc107** ("Used oral or IV prednisone/steroids for asthma")

Date/Time	User	Comments
08/28/2014 12:42pm	kblake	Spoke to parent. Participant did not use steroids.


The balloon will now be yellow to indicate an entry was made. Click on the yellow balloon to see your comment and any other comments that were made for this data point:


**Field Comment Log**

This pop-up displays all the field comments for the record and field specified below. Users with access to data entry forms may leave one or more comments on any field on a data collection instrument, after which the balloon icon will stay lit up to signify that comments exist for that field for this record. All field comments for all records/fields can also be viewed, keyword searched, and filtered on the [Field Comment Log](#) page in this project. NOTE: If you wish to prevent all users in this project from editing or deleting field comments below, see the Additional Customizations popup on the Project Setup page.

Record This is the primary key for this project. It is created using the participant ID and date for the submission: [2\\_2013-07-25](#)

Field: **dc107** ("Used oral or IV prednisone/steroids for asthma")

Date/Time	User	Comments
 08/28/2014 12:43pm	kblake	Spoke to parent. Participant did not use steroids.
08/28/2014 12:45pm	kblake	

Then you can click on the H with the circle to view your edit:

Data History for variable "dc107" for record "2_2013-07-25"		
<p>Listed below is the history of all data entered for the variable "dc107" for Record This is the primary key for this project. It is created using the participant ID and date for the submission. "2_2013-07-25". The data history results are sorted from earliest to most recent.</p>		
Date/Time of Change	User	Data Changes Made
08/28/2014 12:41pm (most recent data change)	kblake	Yes (1)
<div>Close</div>		

### 3. Tracking Study Staff Effort (Time) on MICT and LASST

#### Overview

- Time spent doing study related tasks and procedure are being collected for a study endpoint to measure efficiency – **this is a critically important endpoint for the project**
- Any study staff working on MICT or LASST are to record time for all processes, procedures, phone calls etc for MICT or LASST
- Time is recorded on paper forms and then transferred to the MICT-data REDCap project after each Clinic or FaceTime visit (**Under Construction-how it will be entered into REDCap has not been finalized**)

#### Procedures

- Forms are located on the S drive. (*Click here to go to the blank form for LASST: [Time Tracking Form LASST.xlsx](#).)* (*Click here to go to the blank form for MICT: [Time Tracking Form MICT.xlsx](#).)*
  - Different forms are used for MICT and LASST
  - LASST has 12 study visits so you won't need Visits 7-12 for MICT time tracking
- LASST time tracking will continue for all 12 visits to allow for more data to analyze
- If some aspect of the study are done by multiple persons, each person must be completing the form
- Stopwatches/timers are to be kept at your desk or on your person to keep accurate track of time when doing any study related tasks
  - Additional stopwatches/timers are available by contacting the AC

### 4. Study Visits / Participant Contacts

#### 4.1. General overview of order of procedures

There is no specified order of procedures except as noted under the specific visits. However at V1 and V6 for those sites collecting exhaled nitric oxide data, the exhaled nitric oxide data must be collected before doing PFTs.

#### 4.2. Screening Steps

##### 4.2.1. Tasks to be Completed Prior to Visit 1-Part 1

#### Overview

- Recruiter identifies participants and assigns Participant ID
- Administrative Coordinator (AC) sets up MyNemours accounts for family
- Participant views study consent video online
- Satisfaction Survey for consent process is sent

#### Time Frame

- Target 3 weeks Visit 1, Part 2 (in clinic)
- Window 2-4 weeks before in-clinic screening

#### Equipment/materials

- Ensure participant family has telephone access
- Ensure participant family has a personal email address

### Tasks: Recruiter

- Identify a potential MICT/LASST study participant.
- Randomize potential participant to MICT or LASST study using the Trial Randomization Database by logging in to the <http://www.jhcct.org/mict/micthome.asp>
- Contact parent of a potential study participant to discuss their child's participation in an asthma research study.
- Speak with the family and participant regarding the only the study they are randomized to by the study database
- If family is interested, obtain verbal ACT score and review screening questions to determine eligibility.
- If the child appears to be eligible and is randomized to LASST, follow LASST protocol
- If the child appears eligible and is randomized to MICT
  - verify contact information, including the best time and method to contact the parent, and obtain an email address from the parent so a link for the study website can be sent to the parent and participant.
  - If the family does not have an email account, they will receive instructions for setting up a personal email account.
- Recruiter notifies the Administrative Coordinator (AC) that the family is interested and gives AC the contact information, Trial Randomization number, and screening information (ACT, medications)

### Tasks: Administrative Coordinator (AC)

#### **REDCap Steps**

- In the MICT-data REDCap project,
  - Click 'Add/Edit Records', choose the MICT arm and enter participant ID. The first three letters of the participant ID must be uppercase, i.e. JAX101.
  - Enter data into 'Patient Screening Log' form
    - 3 fields in this form may be left blank initially, these are
      - Main reason failed screen or not enrolled
      - Successfully completed V1 (enrolled)
      - Notes
    - Set form status as 'unverified' if proceeding to consent process
    - Set form status as 'complete' if failed screen
    - Click 'Save Record'
  - Enter data into 'Study Information' form
    - Enter data into all but 'Treatment arm'
      - The field 'Additional email address for alert messages' should be completed if a Study Coordinator (SC) from a site other than the one indicated in the form will be following the participant. Otherwise, the field can be left blank.
      - Be sure to answer 'Is this record for a rescreen?'
        - 'No' is necessary for email invitations to be sent for the Satisfaction Survey and the ACT under Event:Screening..
    - Mark form as 'unverified'
    - Click 'Save and go to Next Form'
  - Enter data into the fields of 'Participant Information' form
    - Make sure the parent's email address has been entered into the Participant Info form before saving the scheduled consenting date under Screening [Otherwise the about the consenting appointment will bounce back (and not get to the parent's email address) because it is sent immediately after entering the consenting appointment date and saving the form.
    - Mark form as 'Unverified'



- Click 'Save Record'
  - Enter the date and time of the Consenting Phone Appointment in the 'Visit Dates' form under 'Screening'.
    - Mark form as 'unverified'
    - Click 'Save Record'
- In the MICT-web info REDCap project
  - Click 'Add/Edit Records' and choose the next available ID from the dropdown list of incomplete records
  - Enter participant ID used in MICT-data. The first three letters of the participant ID must be uppercase, i.e. JAX101.
  - Click 'Save and Continue' then send email as described in step called 'Send email'
  - Enter date the participant will be given ID
  - Set the 'Basics' form as 'unverified'
  - Click 'Save Record'
  - 'Send email entitled "**Subject: Next steps for the Asthma Research Study**" (**Click this link to see all emails sent to study participants: [Emails Sent to Participants](#).**)
  - Email is sent to parent's PERSONAL email address within 24 hrs after the recruiter has scheduled the Consenting Phone Appointment using the webpage [https://apps.nemoursresearch.org/mict/admin/about\\_study\\_email.php](https://apps.nemoursresearch.org/mict/admin/about_study_email.php). This message informs the parent that they should expect a call about setting up a MyNemours account and includes the Consenting Phone Appointment date and time.
- In the MICT-equipment REDCap project
  - Click 'Add/Edit Records' and chose the username assigned this participant
  - Click 'Tracking Information' in left side panel under Data Collection
  - Mark that the Username is: 'Assigned- given to potential participant'
  - Enter the Participant ID
  - Click 'Save Record'

***MyNemours Steps (Click here to see [MyNemours section in this MOP](#))***

- MyNemours accounts will be set up for the parent and the child. (Nemours typically sets them up for the parent on behalf of the child so for the study, the child will have a MyNemours account also)
- Both the parent and child will need to activate their individual MyNemours accounts
- MyNemours accounts are used to send the Parental Permission form to the parent and the Assent form to the child from EPIC. This is the only time the MyNemours accounts are used for the study.
- Families can initiate setting my MyNemours accounts at <http://www.nemours.org/patientfamily/mynemours.html>.
- The AC can assist families with accessing the MyNemours link on the webpage, and with filling out the form from the "Request an Activation Code online" link on Nemours.org.  
 \*\*If they are not at a computer, staff will send them the link from the [asthmaaresearch@nemours.org](mailto:asthmaaresearch@nemours.org) email address with instructions and will follow up within 48 hours.

***EPIC Steps***

- The AC contacts the family after verifying whether the child has an EPIC guarantor account. AC will set up an EPIC account if they don't have one.

***Setting up for the Consenting Phone Appointment***

- Four days before the Consenting Phone Appointment, two messages will automatically be sent. (***Click this link to see all emails sent to study participants: [Emails Sent to Participants](#)***)
  - Email #1 Sent to the parent's personal email address:
    - Includes the date and time of the Consenting Phone Appointment, a link to the study video website. The email includes the user name and password which will allow the family to view the consenting video and other dynamic content on the MICT Study Website. This message also includes information about the study email account assigned to the participant.
  - Email #2 Sent to the participant's study email address
    - Includes the date and time of the Consenting Phone Appointment, a description of what will happen during the phone call, a link to a pdf with an ice cream label and instructions to print or save the document. These messages will also be blind-copied to the SC using a site specific email alias.
      - Check the messages that you receive to make sure the phone appt date, username, password and parent's first and last name appear in the messages. When these messages are sent, fields in the 'Email Triggers' form under 'Screening' in the REDCap project MICT-data will be completed.
  - To resend these messages, you may forward the copy you received or do the following in the MICT-data REDCap project:
    - Click 'Add/Edit Records' and chose the participant ID
    - Click the button for 'Email Triggers' under Screening
    - Reset the field for the message you want to resend by clicking 'reset'
    - Click 'Save Record'
    - This will trigger the sending of the message the next morning if the Consenting Phone Appointment that is recorded in REDCap is in 4 days or less.
- The parent and participant view MICT materials (video, other dynamic content) prior to the Consenting Phone Call.
  - Activity on the Consenting Web Site is tracked and recorded in the MICT-quizzes REDCap project. Tracked activity includes indicating who is watching, starting a part of the video, clicking a tab and clicking a side bar button. To view the tracked activity, go to the MICT-quizzes project and click on 'data' under 'Reports' in the left sidebar. (***Click here to see [Viewing Consent Video](#) section in this MOP***).
- If the potential participant is no longer interested in the study, this should be recorded by doing the following in REDCap.
  - MICT-web info REDCap project.
    - View the report 'Viewing consent site and click on the appropriate username.
    - Set the 'Basics' form as 'complete'
    - Click 'Save and go to Next Form'
    - Click 'No' in the 'Tracking' form
    - Set the 'Tracking' form as 'complete'
    - Click 'Save Record'
  - MICT-data REDCap project
    - Click 'Add/Edit Records' and chose the participant ID
    - Click the button for 'Patient Screening Log" under Screening
    - Complete this form
    - Set form as 'Complete'
    - Click 'Save Record'
  - MICT-equipment REDCap project
    - Click 'Add/Edit Records' and choose the username assigned to this participant



- Click 'Tracking Information' in left side panel under Data Collection.
- Enter data for the following fields
  - Set 'Username is:' to 'Withdrawn – iPad was never delivered'.
- Set the form as 'Complete'
- Click 'Save Record'

### Tasks: Administrative Coordinator (AC) and Study Coordinator (SC)

- Parent and participant review the video and content.
  - At the end of the video they select the button that says *Ready to Enroll*.
    - This generates an email to AsthmaResearch@nemours.org that participant # \_\_\_\_\_ is ready to enroll.
    - This generates an email automatically sent to the participant's study email address that lists the next steps for the study, including the date and time of the Consenting Phone Appointment, and a link to a pdf with an ice cream label and instructions to print or save the document.

The AC, Study Coordinators, and PI have access to the email account folder in their Outlook Inbox.

#### 4.2.1.1. Follow-up Process for Consent Video Viewing Prior to Webex

AC will check the report 'Viewing consent site' in the MICT-web info REDCap project frequently during the 3 days before the scheduled Research Assessment Interview appointment and follow up with potential participants who have not watched the video

- On the day of the appointment, if the parent and participant have not watched the video by 3PM, the AC will contact the SC to update the SC on any contacts made with the family and for further instructions from the SC about the appointment (rescheduling or wait and see).
- The SC or AC will contact the family to determine if the appointment needs to be postponed to later in the day or rescheduled to a different day
- If the family cannot be reached, the AC will continue to try and reach the family the next day

#### 4.2.2. Visit 1-Part 1 (Webex Research Assessment Interview)

##### Overview

- WebEx with SC, Parent, Participant to conduct the Research Assessment Interview (called the Phone Consenting appointment to the families)
- WebEx to conduct the Newest Vital Sign
- Parental Permission Form and Assent sent from EPIC to MyNemours accounts
- Satisfaction Survey for consent process is triggered

##### Time Frame

- Target 2 weeks before V1 - Part 2 (clinic visit)
- Window 1-3 weeks before clinic visit
- Duration of visit 1 to 2 hours

##### Equipment/materials

- Computer access
- Internet / Phone access
- Email address
- Equipment/materials for recording Research Participant Assessment Interview
- Forms (**Click this link to view the forms: [Research Assessment interview forms.](#)**)
  - RESEARCH ASSESSMENT FORM – Female
  - RESEARCH ASSESSMENT FORM – Male
- Activated MyNemours accounts for both parent and participant
- Ice Cream label for Newest Vital Sign

**Tasks: Study Coordinator (SC)**

**SC Tasks Prior to V1 – Part 1** (Phone/Research Assessment Interview)

- Verify in EPIC that both the parent and participant have activated their MyNemours account (***Click here to see [MyNemours](#) section in this MOP.***)
- Confirm the appointment date and time with the family prior to the date of the phone appointment and that the parent and child will both be available for the appointment.
  - Verify that the family has access to the Ice Cream label and a calculator, pen/pencil and paper.

**SC Tasks for V1 – Part 1** (Phone/Research Assessment Interview) (***Click this link to see MOP: [MICT Audio Recording MOP](#).***)

- Contact parent and participant by phone using WebEx Meeting Center per Audio Recording Protocol instructions.
  - **IMPORTANT:** The same parent who completes the Research Assessment interview with the study coordinator at this visit, **MUST** be the same person at Visit 6. Please inform the family of this – you will also enter this information REDCap to help you remember when it is time to do the Visit 6 Research Assessment interview.
- Review the participant's preliminary screening information obtained by the recruiter (ACT questions and medications/medical history) with the parent and child to confirm preliminary eligibility.
- Administer the Research Assessment form. **To avoid missing any questions, make a check mark after each question is asked. (*Click this link to view the forms: [Research Assesment forms](#).*)**
  - RESEARCH ASSESSMENT FORM – Female
  - RESEARCH ASSESSMENT FORM – Male
- Conduct the Newest Vital Sign Assessment
  - *Click this link to see [MICT Audio Recording MOP](#) for details*
  - Ask the parent and child if they would like to use a calculator (this is part of the instructions for the Newest Vital Sign)
  - Write notes on the score sheet of anything that the participant says
    - SC notes on the Newest Vital Sign Assessment paper form will be useful for data analysis
    - Scan the form and save on the S drive at S:\CP&P\CLINICAL TRIALS\CPTR STUDIES\MICT Grant\Forms\Newest Vital Signs Worksheets - With Patient Data (***Click this link to see the folder location: [Folder location for Newest Vital Sign Completed Worksheets](#).***)
- After completing the entire Research Assessment Interview including answering any questions the family is ready to sign consent
  - Inform the family that both the parent and child will receive an email (the personal email address that the family has in EPIC so be sure that is the one that they will check) instructing them to check their MyNemours account inbox.
    - (***Click this link to see all emails sent to study participants: [Emails Sent to Participants](#).***)
  - Inform the family that they will sign the PPF and Assent forms electronically
  - Inform the family that after they sign the PPF and Assent forms, they will receive an email to the study email for the parent to complete the Satisfaction Survey for the consent process.
- Schedule Visit 1 Clinic Visit while you still have the family on the phone! If you are conducting the Research Assessment Interview for a coordinator at another site, you should tell the family that the local coordinator will follow up to confirm the appointment.
- Sending the Parental Permission Form and Assent Form
  - Instruction with screen shots on how to send the PPF and assent forms from EPIC to the family's MyNemours accounts for parent and child is available on the S drive.

(Click this link to view the manual: [Manual for Sending PPF and Assent via EPIC and MyNemours.](#))

- Send the PPF and Assent immediately after the Research Assessment interview is completed.
- After saving the audio files according to the steps in the MICT Audio Recording MOP (Click this link to see MOP: [MICT Audio Recording MOP](#)), send an email to Alex Taylor ([Alexandra.taylor1@nemours.org](mailto:Alexandra.taylor1@nemours.org) and [holly.antal@nemours.org](mailto:holly.antal@nemours.org)) to let them know you have completed the recordings and saved them to the shared drive. Include the Participant ID in the email.
  - Please not the “1” in Alex Taylors email (otherwise it will to to a physician in Delaware)
- **The AC is to check the participant’s EPIC account encounters to view the signed PPF and Assent and follow up with families who have not signed**
  - The AC will let the SC know when the PPF and Assent are signed because the SC will need to verify all the responses on the PPF and Assent and make sure that they have agreed to participate.
  - If after 7 days, the PPF and assent are NOT signed, the AC will ask the SC to follow up with the family
  - In EPIC you will be able to see when the MyNemours email was read

### SC REDCap Steps

- **REDCap Instructions (for SC):**
  - [In the MICT-data REDCap project](#)
  - Click ‘Add/Edit Records’ and choose the participant ID (for example JAX122) for this participant
  - Enter the Visit Dates form for the Screening event
    - For the field “Actual visit date” Click the ‘Today’ button or enter the date the phone visit occurred.
      - When a date is entered in this field and saved, MyNemours instructions are automatically sent to the study gmail address, the parent’s email address and the alert email addresses for the site and participant. The message will automatically be sent the first the date is saved. To send the message again, go to the Email Triggers form, reset the appropriate field and save. Then return to the Visit Dates form for the Screening event, enter a date for ‘Actual visit date’ if there isn’t one already and click ‘Save’. When ‘Save’ is clicked, the email messages will be sent.
    - Set form as ‘Complete’
    - Click ‘Save’
  - Enter the Research Assessment Interview form for visit 1.
    - Complete the Research Assessment Interview form for visit 1
    - PDF file with the questions to ask participants is available in this REDCap form.
    - Set form as ‘Complete’
    - Click ‘Save’
  - Continue in REDCap to the Newest Vital Sign Assessment
    - From the grid in REDCap
    - Enter the form ‘Newest Vital Sign’
      - Complete the Newest Vital Sign form while performing the assessment
        - Click ‘Save and Continue’ at any time there is a delay in the responses
        - The number of correct answers will automatically be calculated when answers to all the questions have been entered.

- Click 'Save and Continue' after completing the parent interview.
- After completing the participant's interview, set the form as 'Complete'
- Click 'Save'

### 4.2.3. Tasks to be Completed Prior to Visit 1-Part 2 (Clinic Visit)

#### Overview

- Emails on how to access Gmail account automatically sent
- Complete the [User name Passwords Gmail AppleID](#) form to go with iPad to site
- Study Questionnaires sent to participant
- AC REDCap data entry
- SC reviews ACT and Screening Form completed by participant
- SC Reviews questionnaires completed by participant

#### **Administrative Coordinator (AC) Tasks**

##### **AC REDCap Steps after Consents have been Signed**

- PPF and Assent signed by parent and participant
  - MICT-data REDCap project
    - Click 'Add/Edit Records'
    - Complete the 'Signed consent' form (2 fields)
    - Set form as 'complete'
    - Click 'Save'.
      - This triggers an email (this is the 2nd time this information will have been sent) to the parent's PERSONAL email account on how to access the study gmail account.
      - This triggers 3 emails to the participant's study email address with links to the ACT and SC forms and the Satisfaction Survey. The Satisfaction Survey is for the parent only.
      - ***(Click this link to see all emails sent to study participants: [Emails Sent to Participants.](#))***
      - AC will check to insure that the ACT and SC forms are completed and call family if reminders are needed.
    - Go to the 'Participant Information' form and record whether or not consent was given to send spirometry results to the primary physician for asthma care.
    - Click 'Save'.
- Setting up for V1 Part 2 (if ACT and SC forms meet eligibility criteria; see below **SC REDCap Steps after Consents have been Signed**)
  - MICT-data REDCap project
    - Click 'Add/Edit Records' and choose the participant ID for this participant
    - Enter data into the Visit Date form for Visit1
      - Enter the Target date (can be same as scheduled date) and Scheduled date and time
      - Leave the field 'Is the scheduled visit date within 4 days?' blank unless you want email messages with links to surveys for visit 1 to be sent immediately.
      - Set the form as 'Unverified'
      - Click 'Save'
      - This will take you back to the grid for this participant
    - Enter Target dates in the Visit Date form for Visit 2 and Visit 3
      - These dates are necessary for the functions that display the Asthma Action Plan
- Automated REDCap steps for V1 Part 2

- Four days before V1 the participant will receive
  - another email (this is the 3<sup>rd</sup> time this information will have been sent) to the parent's PERSONAL email account on how to access the study gmail account
  - an invitation to complete the following forms: ACT, Baseline Assessment (BA), Children's Health Survey (CHSA-Child), EQ-5D, and Quality of Life Questionnaires. (If age at consent is <15 years, then the Quality of Life Questionnaire invitation will not be sent.)
    - It is desirable that at least 24 hours before scheduled visit participants will need to complete these forms, giving the coordinator time to review the answers prior to Visit 1.

## **AC REDCap Steps after Visit 1 – Part 2 has been Scheduled**

### **To prepare for the onsite Visit 1**

#### In the MICT-equipment REDCap project

- Click 'Add/Edit Records' and chose the username assigned this participant
- Click 'Name' in left side panel under Data Collection
  - Set form as 'Complete'
  - Click 'Save and go to Next Form'
- Click 'Tracking Information' in left side panel if not already in the form.
- Enter data for the following fields
  - Date iPad was delivered to participant
  - EasyOne spirometer serial number
  - EasyOne asset tag #
  - Date EasyOne was delivered to participant
  - If appropriate, Hotspot serial number and date Hotspot was delivered to participant
- Click 'Save Record'

#### In the MICT – DC summary REDCap project (DC means Diary Card)

- Click 'Add/Edit Records' and enter the participant ID for this participant. The first three letters of the participant ID must be uppercase, i.e. JAX101.
- Enter data into 'Participant Information' form
- Select from status as 'Complete'
- Click 'Save Record'

Complete the 'User name Passwords Gmail AppleID' form and store on the S drive and print a copy to be included with the iPad sent to the site. **Click here to go to the folder: [User Name Password Form](#)**.

## **Study Coordinator (SC) Tasks**

### **SC REDCap Steps after Consents have been Signed**

- Review submitted ACT and SC forms.
  - If the ACT score is <20, the SC will have received an email alert with this information
  - If the SC has generated any email alerts, they need to be resolved
    - **Click here to see the [Viewing All Alerts on My Participant](#) section in this MOP** for instructions on how to review all alerts for the participant
  - If the ACT and SC data indicate that there are issues to be resolved then the Visit 1-Part 2 (clinic visit) may need to be rescheduled (they may be eligible for V1 in 4 weeks).
    - If the Visit 1-Part 2 (clinic visit) does need to be rescheduled, then be sure and change the date in REDCap. Otherwise, the emails with the questionnaires will be sent out 4 days/3nights before the 'scheduled date' in REDCap. This would result in confusion on the part of the participant when the emails are sent out for the revised Visit 1-Part 2 (clinic visit) date.

- If there are any issues that have been discussed with Dr. Blake and an exception has been allowed, document the exception on the 'Protocol Exception' Form under the Ongoing column.
- The EasyOne Spirometer can be set up with all the general information that you have on the participant except height and weight which are collected at the Visit 1 – Part 2 clinic visit
  - See Coordinator Instructions for using the Easy One. *(Click this link to view the manual: [Coordinator Manual for EasyOne Use.](#))*

#### **SC REDCap Steps after Visit 1 – Part 2 has been Scheduled**

- Review participant's responses to the ACT, Children's Health Survey, EQ-5D, Quality of Life Questionnaires (if 15 yo or older) and the Baseline Asthma and Medical History and check the BA Form Alerts.
- If there are any issues that have been discussed with Dr. Blake and an exception has been allowed, document the exception on the 'Protocol Exception' Form under the Ongoing column.
  - **To review the submitted forms, go to the MICT-data REDCap project**
    - Click 'Add/Edit Records' and chose the participant ID for this participant
    - Review the following REDCap forms under Visit1
      - Asthma Control Test – participant version
      - Children's Heath Survey – participant version EQ-5D from the EuroQol Group
      - Quality of Life Questionnaires
        - If 15 yo or older when the consent was signed
        - This form has a notes field for your comments.
      - Baseline Asthma and Medical History – participant version
        - This form has a notes field for your comments
      - BA Form Alerts
        - Fields will appear in this form, depending on the answers given for the Baseline Asthma and Medical History
        - This form has a notes field for your comments
        - Set form as 'Complete' to signify that the BA Form Alerts were reviewed.
    - Click 'Save' on each form as comments are added

#### **4.2.4. REDCap steps: Participant Discontinues Between V1 Part 1 and Part 2** **When a participant discontinues the study after Visit 1 – Part 1 (they have completed the consent process) but before they have Visit 1 – Part 1 (clinic visit), the AC should do the following in REDCap**

In the MICT-data REDCap project

- Click 'Add/Edit Records' and choose the participant ID for this participant
- Click the button for 'Patient Screening Log' under Screening
  - Complete form
  - Set form as 'Complete'
  - Click 'Save Record'

In the MICT-equipment REDCap project

- Click 'Add/Edit Records' and choose the username assigned to this participant
- Click 'Tracking Information' in left side panel under Data Collection.
- Enter data for the following fields
  - Set 'Username is:' to 'Withdrawn – iPad was never delivered'.
- Set the form as 'Complete'
- Click 'Save Record'

In the MICT-web info REDCap project



- Click 'Add/Edit Records' and choose the username assigned to this participant
- Go to the 'Basics' form if not already there, using the left side panel
- Set the form as 'Complete'
- Click 'Save Record'

### 4.3. Visit 1-Part 2 (Clinic Visit)

#### Overview

- Determine that iPad is ready for participant
- Set up EasyOne for participant
- Conduct Visit 1 procedures
- Dispense open-label Advair 250/50 and Proair
- Dispense other study items to participant
- Confirm shipping address and details for study medication delivery

#### Time Frame

- Target: 8 weeks prior to Randomization (V3)
- Window: 6 to 10 weeks prior to Randomization (V3)
- Duration of V1: 2 to 4 hours

#### Equipment/materials

- NIOX MINO (if being performed at your site)
- EasyOne Spirometer and that includes 4 spirettes
- Nose Clips (may need to dispense several for the participant to take home)
- Nemours nylon bag
- Open-label Advair and Proair
- Pregnancy test kit
- Equipment agreement form. (*Click here to view the form: [Equipment Use Agreement.](#)*)
- CT Payer Information (*Click here to see [Participant Stipends using CT Payer](#) section in this MOP.*)
- Yardstick for measurement during virtual visits
- Coordinator's iPad so physician can complete physical exam in REDCap
- iPad2 with Defender case
  - FaceTime Instructions on YouTube <http://youtu.be/CoU38SyU8fo>
  - FaceTime tutorial: <http://www.youtube.com/watch?v=CoU38SyU8fo>
  - Completed copy of the [User name Passwords Gmail AppleID](#) form. *Click here to go to the folder: [User Name Password Form](#)*

#### Procedures Overview:

**Note:** Any participant without an asthma care provider is to be referred to one.

- Conduct pregnancy testing if participant is female of childbearing potential
- Physical Exam including height and weight, and anthropomorphic measurements
- Measure exhaled nitric oxide (eNO). This must be completed before pulmonary function testing.
- Pulmonary function testing pre-and post-bronchodilator, using the participant's EasyOne spirometer
  - **Note:** if FEV1 is less than 70% predicted participant is not eligible
- Administer "Ask in Private" questions to participant in a location away from parent
- Review Temporary Asthma Action Plan
- The Actual Visit Date for Visit 1 must be entered into REDCap. Do this as soon as you can after arrival.
  - **IMPORTANT FIRST STEP FOR PARTICIPANTS TO ACCESS THE STUDY WEBSITE (MORNING AND EVENING REPORTS)**
  - *Click here to see the [Important First Step](#) section in this MOP.*

- Dispense study medication
  - Confirm shipping address and deliver details with family
- Dispense iPad, EasyOne and other supplies
  - Have family sign Equipment Use Agreement (***Click here to view this form: [Equipment Use Agreement.](#)***)
- Send the Physician Introduction Letter to primary asthma physician (***Click this link to see IRB approved letters to participant Physicians: [Physician Letters.](#)***)
  - Include copy of spirometry results
- Chart in EPIC with a brief summary of visit

### 4.3.1. Study Coordinator Procedures for Visit 1 – Part 2

#### 4.3.1.1. Coordinator Review of Questionnaires

- If not all of the questionnaires have been completed before the participant arrives at Visit 1, follow the order of steps outlined in the section 'My participant has not completed all the questionnaires for Visit 1' (***Click here to see the [My participant has not completed all the questionnaires for Visit 1](#) section in this MOP.***)
- If there are any issues that have been discussed with Dr. Blake and an exception has been allowed, document the exception on the 'Protocol Exception' Form under the Ongoing column.

#### 4.3.1.2. Collect in Private

- Leave parent in waiting area
- Obtain height
  - Use the yardstick that will be provided to the family
  - Mark each 12 inches with feet notations
- Obtain weight (This can be done at the same time as Biometrics. (***Click here to see the [Biometrics](#) section in this MOP***))
- can also do Biometrics at this time)
- Obtain vital signs
- Record the "Collect in Private" information
  - Pregnancy/birth control
  - Smoking history
- Record data in REDCap (***Click here to see the [SC REDCap Instructions](#) section in this MOP***)

#### 4.3.1.3. EasyOne Instructions and Practice

- Instruct participant on use of EasyOne using the instruction loaded onto the iPad.
  - (***Click this link to see the participant EasyOne manual, [EasyOne Manual for Participants.](#)***)
- Conduct the pre-bronchodilator pulmonary function testing
  - Document if it has not been 4 hours since the participant last used albuterol or Xopenex
  - Make sure the participant has an FEV1  $\geq$  70% predicted using the predicted calculator found on the ACRC website at <https://www.jhcct.org/Secure/LASST/LASSTPFT.asp>
    - Calculate the % Predicted value as  

$$\% \text{ Predicted} = 100 * [\text{FEV1 (in Liters)} / \text{Predicted FEV1 (in Liters)}]$$
  - You will have the 3 peak flow values that you will need to generate the Temporary Asthma Action Plan
- Administer 2 puffs of ProAir
  - Wait 15 to 20 minutes for ProAir to have bronchodilator effect before doing post-bronchodilator testing
  - Review proper technique



- Use a spacer if desired
- Conduct the post-bronchodilator pulmonary function testing
- Put the EasyOne into the cradle and print the results
  - Print 2 copies (for primary care physician and for site records)
- Dispense EasyOne to the participant along with 4 extra spirette
  - A spirette can be used for about 2 weeks before replacing unless the participant has been ill, then replace sooner
- Record data in REDCap (***Click here to see the [SC REDCap Instructions](#) section in this MOP***)
- Have family sign Equipment Use Agreement (one form for both iPad and EasyOne) (***Click here to view this form: [Equipment Use Agreement](#).***)
  - Email or fax a completed copy of the Equipment Use Agreement form to the AC at ([Stacey.gray@nemours.org](mailto:Stacey.gray@nemours.org) or Fax: 904-697-3799)

#### 4.3.1.4. Exhaled Nitric Oxide

- Collect exhaled nitric oxide results (if your site is collecting exhaled nitric oxide)
- Record data in REDCap (***Click here to see the [SC REDCap Instructions](#) section in this MOP***)

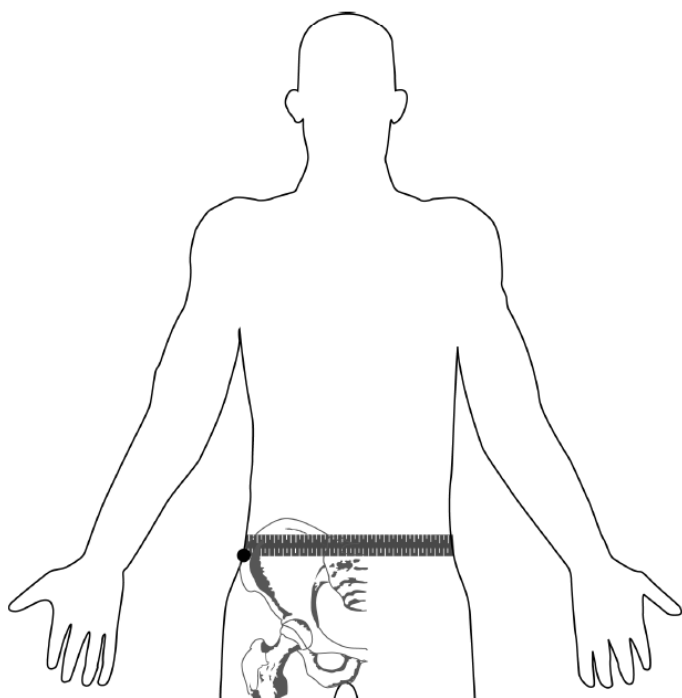
#### 4.3.1.5. Physical Exam

- Have physical exam done
- Record data in REDCap (***Click here to see the [SC REDCap Instructions](#) section in this MOP***)
  - The physician will need to log into their REDCap account to complete the form, electronically sign, and lock the form

#### 4.3.1.6. Biometrics (Anthropomorphic Measurements)

- This can be done at the same time as “Collect in Private”. (***Click here to see the [Collect in Private](#) section in this MOP***)
- You will need a flexible measuring tape
  - NOTE: Many clinical measuring tapes have a “dead space” between the end of the tape and then beginning of the measuring region. Be sure to wrap tape around the “zero” mark on the tape.
- Detailed instructions are available at <http://www.cdc.gov/nchs/data/nhanes/bm.pdf>. A video from the CDC on how to perform the measurements is available at [http://www.cdc.gov/nchs/nhanes/nhanes3/anthropometric\\_videos.htm](http://www.cdc.gov/nchs/nhanes/nhanes3/anthropometric_videos.htm)
- **Waist measurement:** just above hip bone
  - Have participant stand
  - Hold shirt/blouse above the waist and lower pants and underclothing slightly to expose the waist area
  - Palpate the hip area to locate the right ilium (see diagram below)
  - Draw a horizontal line just above the uppermost lateral border of the right ilium and then cross the line to indicate the midaxillary line of the body (per NHANES protocol <http://www.cdc.gov/nchs/data/nhanes/bm.pdf>. )
  - Place the measuring tape snugly around the trunk in a horizontal plane at the level marked
  - Make sure the measuring tape is horizontal with the floor
  - Make the measurement at the end of a normal expiration
  - Measure to the nearest centimeter

Exhibit 3-5. Measuring tape position for abdominal (waist) circumference



- **Hip measurement:** at the widest point
  - Have participant stand with feet together (helps show protuberance of the area when viewed in profile)
  - Place tape measure over largest part – make sure tape measure is horizontal, tighten, but do not compress the skin
  - Measure to the nearest centimeter
- **Neck measurement:** just below the Adam's apple
  - Definitions
    - Frankfort Horizontal Plane – head parallel to the floor looking straight ahead
    - Laryngeal prominence – also known as the Adams apple, located in the throat
  - Participant sits or stands upright with the head in the Frankfort Horizontal Plane
  - Apply tape around the neck just below the laryngeal prominence
  - Measurement is made perpendicular to the long axis of the neck (which is not necessarily in the horizontal plane)
  - Tape should be placed in such a way as to minimize the measurement
  - Measurement should be completed in less than 5 seconds, to avoid participant discomfort
  - Circumference of the neck is measured to the nearest centimeter

#### 4.3.1.7. Pregnancy Test

- Obtain the pregnancy test whenever is convenient using a urine test kit

#### 4.3.1.8. Temporary Asthma Action Plan (Print and Review)

- Obtain the pregnancy test whenever is convenient using a urine test kit
- Print the Temporary Asthma Action Plan out of REDCap
  - The Visit 1 date AND the “target” Visit 2 and target Visit 3 dates **MUST** be entered into REDCap in order for the Temporary Asthma Action Plan to be printed
  - Go to MICT-data REDCap project
    - Under “Project Bookmarks” select “Print Asthma Action Plan”

- Enter the Participant ID
- Print AAP

#### 4.3.1.9. iPad Review

- Obtain the pregnancy test whenever is convenient using a urine test kit
- Verify that family has home wifi
  - If not, provide and set up a HotSpot (this should already be known from previous contact with the family)
  - The video for setting up a Sprint Hotspot is available on the participant's iPad in the 'Home Videos' section of videos. <http://www.youtube.com/watch?v=AoV1jMb0utE>.
- Provide the family with the completed form "**User name Passwords Gmail AppleID.docx**". **Click here to go to the folder: [User Name Password Form](#)**
  - A completed copy of this form can be found in the folder for your site. **(Click here to go to the blank form: [User name Passwords Gmail AppleID.docx](#).)**
    - In this folder (**Click here to go to the folder: [User Name Password Form](#)**), you will see folders for each site. The AC will have the participant form saved in the folder for your site. The SC can print extra copies of the form if needed.
- Review all use of the iPad with the parent and participant
  - The family will receive an email after Visit 1 – Part 2 instructing them on how to access the website if they want to use a computer or smart phone
- A step-by-step guide has been prepared for the coordinator to use in teaching the family all the study related content on the iPad. **(Click this link to view the guide click: [Coordinator Instructions for Training Participants to use iPad at Visit 1](#))** to ensure all necessary areas of using the iPad are covered
- Study email
  - Show how to access study email on iPad and confirm that they have changed the password
  - Tap the Safari icon and go to gmail.com. Follow instructions for changing the password
  - If they have forgotten their original password, they will need to contact the AC
  - or pull up the email sent to their personal email account that had this information
- If the iPad has "remember me", suggest that the family place a check in that box to store the information
- Practice connecting via FaceTime
- Wifi
  - Explain that wifi signal can fluctuate even in their own home and that moving to various locations within their home (or location) may improve the connectivity
- Have family sign Equipment Use Agreement (one form for both iPad and EasyOne) **(Click here to view this form: [Equipment Use Agreement](#).)**
  - Email or fax a completed copy of the Equipment Use Agreement form to the AC at ([Stacey.gray@nemours.org](mailto:Stacey.gray@nemours.org) or Fax: 904-697-3799)

#### 4.3.1.10. Dispense Advair 250/50 and ProAir

- Dispense open-label study drugs (Advair 250/50 and ProAir)
- Instruct on the proper use of Advair
  - Demonstrate using the video on the iPad **(Click this link to view the guide: [Coordinator Instructions for Training Participants to use iPad at Visit 1](#).)**
- **Remind participant that these study drugs replace the ICS/LABA and rescue medications they have been using.**
- Remind them that the dose of Advair is only 1 inhalation 2 times a day (as some ICS/LABA are 2 inhalations for each dose).
- Adherence Monitoring of Advair 250/50
  - Steps to ensure REDCap adherence monitoring starts off correctly for the participant

- If Visit 1 is in the morning (before 3PM) **and** the participant will take their first Advair 250/50 dose **in the clinic** with you
  - Have the participant complete their first Morning Report in the clinic with you
  - Instruct the participant to answer 'Yes' to the question 'Did you start your new Diskus with this dose?'
  - Instruct the participant that after taking their evening dose that night at home, the participant will be prompted to enter the Diskus counter number. Instruct the participant that they should enter 58 since they will have now had 2 doses (58 is the number that should show in the counter window of the Advair Diskus).
  - Instruct the participant to submit the Morning Report and that if they need to revise the entry, they can do so until 3PM
- If Visit 1 is in the afternoon (after 3PM) **and** they have already taken their morning dose of their personal medicine before the appointment **and** the participant will take the first dose of Advair 250/50 with their evening dose **at home**:
  - Instruct the participant to answer 'Yes' to the question 'Did you start your new Diskus with this dose?' on their Evening Report that night.
  - Instruct the participant to enter 59 when prompted to enter the Diskus counter number (59 is the number that should show in the counter window of the Advair Diskus) on their Evening Report that night.
- At Visit 1, **do not** have them take their "evening" dose in the clinic if it is before 3PM (if they have already taken their morning dose of their personal medicine before the appointment). This is because they will only be able to complete the Morning Report at this time on the iPad, yet this will be an "evening" dose of study medication.
- **The Diskus counter number is only prompted for on the Evening Report.**
  - REDCap will perform automatic adherence monitoring during the study. Every 4 days, the Evening Report will prompt the participant to enter their Diskus counter number. They should answer this question AFTER they answer the question "Did you take the evening study Diskus dose?" DO NOT tell the participant we are monitoring adherence.
- The study coordinator will receive an alert on the evening of Visit 1 after the participant submits the Evening Report stating that a new Diskus was started. This email just indicates that the participant took their first dose from their study Advair Diskus.
- CONFIRM STUDY MEDICATION SHIPPING ADDRESS AND FEDEX DELIVERY INSTRUCTIONS
  - Discuss with family what address study medication should be delivered to
  - Instruct family to notify study coordinator if they move
  - Discuss with family if the package can be left at the door, or if there are other instructions

#### 4.3.1.11. Dispense CT Payer Card

- Review instruction for using CT Payer
  - Review instances that may incur a fee on their CT Payer card.
  - Inform participants there are certain fees that could occur. Review the Cardholder FAQ. (***Click this link to view the FAQ click the link: [Cardholder FAQs & Fee Schedule.pdf](#).***)
  - Email the MICT # on the card to the AC ([Stacey.gray@nemours.org](mailto:Stacey.gray@nemours.org))
    - The MICT # is where the cardholder name would normally appear (e.g. Nemours MICT 22)
    - The AC needs this to process payments for participants

#### 4.3.1.12. Chart in EPIC

- Chart in EPIC with a brief summary of visit

#### 4.3.2. Study Coordinator REDCap Instructions

During **Visit 1 Part 2 (Clinic Visit)**, SC should complete the following.

- The Visit 1 date must be entered into REDCap. Do this as soon as you can after arrival.
  - **IMPORTANT FIRST STEP FOR PARTICIPANTS TO ACCESS THE STUDY WEBSITE (MORNING AND EVENING REPORTS)**
- If you still encounter a problem with the participant accessing the study website, go to MICT-data REDCap project, Screening, Signed Consent form
  - Make sure that “Successfully completed consent process” is set to ‘Yes’
- If you are still having trouble follow the same steps as found in this section on what to do if your participant has not completed all the questionnaires prior to Visit 1 (***Click here to see the [My participant has not completed all the questionnaires for Visit 1 section in this MOP](#)***). Per this link you may need to reset the iPad to clear out any cookies; you will then need to re-log in with the username and password but after logging in this time, the participant won’t have to put in their username and password next time.

In the MICT-data REDCap project

- Click ‘Add/Edit Records’ and chose the participant ID for this participant
- Go to the ‘Visit Dates’ form under Visit 1
  - Complete the field for ‘Actual visit date’
  - Set form as ‘Complete’
  - Click ‘Save’
  - **Note:** When a date for this field has been saved, the participant is automatically given access to the Trial website (and Morning and Evening Reports) when logging in. If no date has been saved, the participant only has access to the Consent website when logging in. The email “Completing Morning and Evening Report When You Don’t Have Wireless Internet Access” will automatically be sent at 4 am the day after the date stored in ‘Actual visit date’.
- Go to the ‘Collect in private’ form
  -
- Go to the ‘Collect in private’ form
  - Complete the fields as the information is collected
  - Set form as ‘Complete’
  - Click ‘Save and go to Next Form’.
- Go to the ‘Biometrics’ form if not already there
  - Complete the fields as the information is collected
  - Set form as ‘Complete’
  - Click ‘Save and go to Next Form’
- Go to the ‘Nitric Oxide’ form if not already there
  - Complete the fields as the information is collected.
  - Set form as ‘Complete’
  - Click ‘Save and go to Next Form’
- Go to the ‘Pulmonary Function Testing’ form if not already there (this information is needed for the Asthma Action Plan (AAP) so that you can demonstrate the AAP to the family during the visit)
  - Complete the fields as the information is collected.
    - During this process, you will go to <https://www.jhcct.org/Secure/LASST/LASSTPFT.asp>
    - Log in with the generic user name and password you would use to access the ACRC Website.
  - Set form as ‘Complete’
  - Click ‘Save and go to Next Form’
- Go to the ‘Temp Asthma Action Plan’ form if not already there.

- Complete the fields as the information is collected.
- Click 'Save and Continue'
- NOTE: This must be done for the Temporary Action Plan to appear on the following link and on the Trial website when the participant logs in.
- Follow the link to <https://apps.nemoursresearch.org/mict/admin/actionPlan.php> to print the Temporary Asthma Action Plan for the participant on an 8.5x11 page. A link to this web page ('Print Asthma Action Plan') is also available in the left sidebar under Project Bookmarks.  
User name and password for this site is your REDCap user name and password.
- Go to the 'Drug Accountability Log' form
  - Click on the circle to see records
  - Enter information in the following sections of this form
    - First Proair albuterol inhaler provided
    - First diskus provided – Advair 250/50
  - Complete the appropriate fields from the below options:
    - Drug name
    - Expiration date
    - Lot number
    - Mode of transport
    - Tracking number (if shipped)
    - Delivery Status
    - PDF of delivery confirmation
    - Date of study drug return
  - Set to 'Unverified'
  - Click 'Save Record'
- Go to the 'MICT – drug accountability by site' form under Project Bookmarks (note: you are NOT in a specific participant's record, this is a Center Level record)  
Purpose: To enter data (when receiving or dispensing drug):
  - Click 'Add/Edit Records' and click 'Add new record' - (Underneath 'Incomplete Records' and 'Complete Records')
  - Complete the 'Drug Accountability Log' form (this is for the Center Level drug accountability)
    - Manufacturer
      - GlaxoSmithKline is the manufacturer for Advair 250/50
      - Teva Respiratory, LLC is the manufacturer for Proair
    - Number of Diskus in this transaction, enter '1'
    - Click 'Dispensed'
      - Click 'Dispensed to participant'
    - Remaining balance....
      - Enter the number of Advair 250/50 you now have remaining at your site (this is why you need the information from the 'MICT – drug accountability by site' form)
  - Set the form status as 'Complete'
  - Click 'Save' or click 'Save and Continue' if creating a pdf for the transaction
  - Repeat above steps for the ProAir dispensed
- To view a report of transactions for a single medication
  - Click on the name of the report in the left panel under 'Reports'
    - To print report, click 'Print page'
    - To download report as an Excel file, click 'Microsoft Excel (CVS)'
- To create a pdf file of a single transaction
  - Enter a record by doing one of the following:
    - Click 'Add/Edit Records' and select the records from the drop-down list.



- Click on the Entry ID in a report of transactions
- Click 'Save and Continue' after entering data
- Click the 'Download PDF of instrument(s)' button
- Select 'This data entry form with saved data'
- Click the radio button next to 'Save File'
- Click OK

**During Visit 1 Part 2 (Clinic Visit), the physician performing the physical exam should complete the following.**

Log into REDCap

In the MICT-data REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
- Click the button for 'Physical Exam' under Visit1
- Complete the fields in this form as the exam is performed.
- Set the form as 'Complete'
- Check the 'Lock' and 'E-signature' options.
- Click Save 'Record'

Log out of REDCap

Notes: Any physician with a REDCap username and access to the REDCap project can e-sign the Physical Exam form of any participant at any time. E-signing in REDCap consists of checking the boxes next to 'Lock' and 'E-signature' and saving the record. The status of the form can be set to 'Incomplete', 'Unverified' or 'Complete' when the form is e-signed and the status is locked along with the other fields on the form. Once a form is e-signed, it must be unlocked before any changes can be made.

Only REDCap users who have the user right to lock and e-sign a form can see the check boxes for locking and e-signing the form. Forms that are locked and e-signed will have a padlock and green shield (with check) in the event grid. Also, forms that are locked and e-signed will not have buttons for saving the form at the bottom of the page when viewing the form.

Study coordinators can change the status of the Physical Exam form before the form is e-signed.

In EPIC, the physician will need to go to the participants record "Allergies" and complete that allergies were reviewed on the Visit 1 date. **This is important because** at Visit 6 you may want the physician to call in a Rx for a 30 day supply of the controller medication they were one during the study (to last them until they can be seen by their asthma PCP). If this is not done in EPIC, then the Rx will not be able to be sent to the pharmacy as allergies must be reviewed every 180 days in EPIC.

#### 4.3.3. Administrative Coordinator REDCap Instructions

In the MICT-data REDCap project,

- Click 'Add/Edit Records' and chose the participant ID
- Click the button for 'Patient Screening Log' under Consent
- Complete form
- Set form as 'Complete'
- Click 'Save Record'

After adding \$25 is added to participant's CTPayer account (within 24 hours of visit), record this in REDCap.

In the MICT – DC summary REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant

- CTPayer account number can be viewed in 'Participant Information' form
- Click the button for 'Clinic and FaceTime Visits'
- Record whether credit was added to form and date this was done
- Click 'Save Record'

In the MICT-equipment REDCap project

- Click 'Add/Edit Records' and chose the username assigned this participant
- Click 'Tracking Information' in left side panel under Data Collection.
- Enter data for the following fields
  - Participant ID
  - Date iPad was delivered to participant
  - EasyOne spirometer serial number
  - EasyOne asset tag #
  - Date EasyOne was delivered to participant
  - If appropriate, Hotspot serial number and date hotspot was delivered to participant
- Set the form as 'Unverified'
- Click 'Save Record'

#### 4.3.4. Alerts to Study Participant after Visit 1

The day after visit 1, an email message with instructions that Morning and Evening Reports can be completed on any computer or smart phone with internet access will automatically be sent to the participant's study email address. This is because we know that they may not have the iPad every time they need to complete the morning or evening reports and this provides an alternative way to input the data. **(Click this link to see all emails sent to study participants: [Emails Sent to Participants.](#))**

#### 4.4. Visit 2 (Virtual Visit)

##### Overview

- Ensure participant meets criteria for continuation (view the 'Assessment for Stable Phase' form in REDCap)
- Review questionnaires prior to FaceTime visit
- Conduct FaceTime Visit
- Do pre- and post-bronchodilator spirometry
- Do a random check of PEF values on participants EasyOne
  - Select a date for PEF value from "Peak Flow Report" in REDCap (note the date and PEF value)

##### Time Frame

- Target: 4 weeks prior to Randomization (V3)
- Window: 4 to 6 weeks prior to Randomization (V3)
- Duration of V2: 1 hour

##### Equipment/materials

- iPad
- Coordinator EasyOne Spirometer (in case you need to show them anything via FaceTime)
- Visit 1 height and weight data (to compare with Visit 2)
- Latest data on Advair Diskus counter number from REDCap

#### 4.4.1. Study Coordinator Procedures for Visit 2

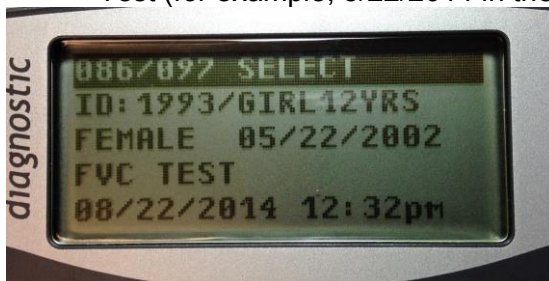
- If there are any issues that have been discussed with Dr. Blake and an exception has been allowed, document the exception on the 'Protocol Exception' Form under the Ongoing column.
- Ask participant for current height and weight
  - If height and weight have changed since V1, then you will need to do at least 1



effort before you can update the height and weight data

- Changing height and weight data will change it for the present test and all subsequent tests
  - **Click here to see a summary of height data:** [Height Data Summary in REDCap.](#)
- EasyOne Spirometry – follow the instructions in the Coordinator EasyOne Manual (**Click this link to view the manual:** [Manual for Coordinator EasyOne Instructions.](#))
  - Document if it has not been 4 hours since the participant last used albuterol or Xopenex
  - Have participant do 3 pre-bronchodilator efforts.
  - Take picture of the flow volume curves using your iPad by holding down the power button at the same time as holding down the home key
    - These are saved to ensure we have data should the EasyOne get lost or broken
    - Save the photos on the shared drive at this location (**Click this link to see the location:** [Folder for iPad Photos.](#))
    - Use the following format for creating a folder name for file saving:  
**JAX102\JAX102V5\_07-10-14**
  - Record the PFT Data using the MICT PFT Worksheet. (**Click here to view the PFT FaceTime Worksheet.**)
    - Ensure FEV1 is still  $\geq 70\%$  predicted using the predicted calculator found on the ACRC website at <https://www.jhcct.org/Secure/LASST/LASSTPFT.asp>
    - Calculate the % Predicted value as  

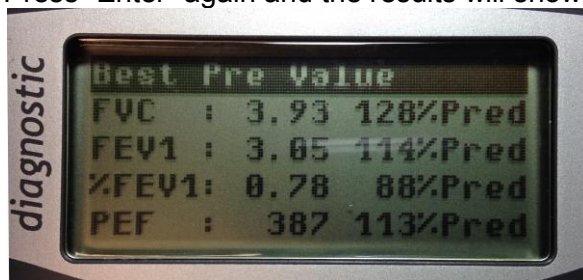
$$\% \text{ Predicted} = 100 * [\text{FEV1 (in Liters)} / \text{Predicted FEV1 (in Liters)}]$$
    - Have participant take 2 puffs of ProAir and wait 15 minutes
      - Can end FaceTime and restart in 15 minutes
    - Have participant do 3 post-bronchodilator efforts using same procedure as for pre-bronchodilator testing
    - Save the handwritten PFT Worksheet until the end of the study.
      - This worksheet will be needed in order to reconcile all the PFT data downloaded from the EasyOne device at Visit 6 with the data entered into REDCap.
- Do a random check of PEF values on participants EasyOne
  - From the REDCap “Peak Flow Report”, select 3 dates and write down the 3 PEF values for each of the 3 dates. Or you can print the Peak Flow Report. Do this when getting prepared for the FaceTime visit (you can do this a day or two before the visit date).
  - Instruct the participant turn on EasyOne
    - Go to “View Results” on EasyOne by pressing the right arrow key and pressing “Enter”
    - Use the right arrow button to tab to “Date”
    - Have the participant enter the first date you have selected and press “Enter”
    - Ask the participant to tell you the date on the screen; it will be under FVC Test (for example, 8/22/2014 in the image below)



- - If the participant DID do the PEF, then the date on the screen will match the date you asked them to enter
  - If the participant DID NOT actually do the PEF on the EasyOne on

that date (even though they entered data on the Morning Report for that date, i.e. they made up numbers on the iPad Morning Report), the EasyOne will search for the closest date prior to the date you instructed the participant to enter.

- Press “Enter” again and the results will show up on the EasyOne screen



- - Ask the participant to tell you the PEF number (387 in the image above)
  - Compare the 3 PEF values that were entered into REDCap with the PEF that is on the EasyOne. If they actually did the PEF on that date, then one of the 3 values in REDCAP will match with the value that they show on the EasyOne.
    - Note: Unfortunately, the EasyOne will only show you the PEF that is associated with the best sum of the FVC and FEV1 which is not always the highest PEF. But when you download all the data from the EasyOne, you can see every effort that that the participant made on the EasyOne for that date.
  - Repeat the above for the other 2 dates (and 3 PEF values for each date) you selected from the REDCap data
  - If the participant tells you that they don't have that date for any of the 3 dates viewed and the PEFs don't match up, then counsel the participant to enter only REAL values into the Morning Report.
    - Important for triggering their Asthma Action Plan to pop up on the iPad
    - Important for us to monitor their safety
- View counter on Advair Diskus and confirm that it is consistent with what is in REDCap
- Review any adverse effects, alerts, or any other issues
- Review criteria included on the 'Assessment for Stable Phase' form in REDCap Visit 2
  - If the participant meets any of these criteria, they are not eligible to continue but may be re-screened. **Click here to see [Rescreening](#) section in this MOP.**
- Confirm Visit 3 FaceTime date and time
  - Please make every effort to complete Visit 3 BEFORE the participant would run out of the 2<sup>nd</sup> provided diskus of Advair 250/50
- Confirm study medication shipping address and fedex delivery instructions
  - If there are any changes from previous visit, notify the Pharmacist (at WIL or ORL) or AC (for other sites)
- Remind participant to check emails every few days and 4 days before Visit 3 for the upcoming visit questionnaires
- Remind participant to have height and weight done before the Visit 3 FaceTime visit
- Chart in EPIC with a brief summary of visit

#### 4.4.2. Study Coordinator REDCap Instructions for Visit 2

Four days prior to the scheduled date, the participant will receive email messages with links to the ACT and Pre-Clinic Visit Survey and instructions to complete these at least 24 hours before their appointment.

**Prior to visit 2**, SC should review participant's responses in the following forms: Asthma Control Test - participant version and Clinic Visit – participant version.

In the MICT-data REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
- Review the following REDCap forms under Visit2-virtual
  - Asthma Control Test – participant version
    - The ACT status form has a notes field for your comments
  - Clinic Visit – participant version
    - This form has a notes field for your comments
  - Assessment for Stable Phase
    - This form has some checks that may indicate the visit should be delayed/
    - This form will need to be reviewed and completed when visit 2 is finished.

Click 'Save' on each form as comments are added

**After completing Visit 2 (FaceTime), SC should complete the following.**

In the MICT-data REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
- Click the button for 'Visit Dates' under Visit2-virtual
  - Complete the field for 'Actual visit date'
  - Set form as 'Complete'
  - Click 'Save'
- Click the button for 'Pulmonary Function Testing' under Visit2-virtual
  - Complete the fields as the information is collected.
    - During this process, you will go to <https://www.jhcct.org/Secure/LASST/LASSTPFT.asp>
  - Set form as 'Complete'
  - Click 'Save and go to Next Form'
- Go to the 'Assessment for Stable Phase' if not already there
  - Complete the fields in this form. This will include:
    - Reviewing clinic visit form (if prompted)
    - Reviewing diary card alerts
      - A summary of alerts can be viewed in the report 'data' in the REDCap project, MICT-alerts. **Click here to see [Alerts About My Participant](#) section in this MOP.**
      - Summary of diary card submission date and dose taken can be viewed with the tool at [https://apps.nemoursresearch.org/mict/admin/diary\\_submission.php](https://apps.nemoursresearch.org/mict/admin/diary_submission.php). **Click here to see [Viewing Study Drug Use and Reports](#) section in this MOP.**
      - A summary of "urgent and unscheduled medical attention" alerts can be viewed as a report in the MICT-diary cards project and selecting "Questions about urgent unscheduled medical attention" in the Reports section on the left side
  - Set form as 'Complete'
  - Click 'Save'
  - Note: If any of the items on this form are checked, the participant does not meet criteria for "stable phase" and is NOT eligible to continue in the study. The run-in period must be extended or the participant must be removed from the study and come to the clinic to turn in their iPad and spirometer. **Click here to see [Rescreening](#) section in this MOP** for more information.
- Click the button for 'Visit Dates' under Visit3-virtual

- If visit 3 is not scheduled :
  - Enter a date and time into 'Scheduled date and time'.
    - **TIP:** When determining the date for visit 3, try and schedule it a few days BEFORE the diskus would be expected to run out (if the participant was 100% adherent) or 30 days from visit 2. There is a +/- window of 2 weeks from visit 2, so schedule earlier (suggest 7 days earlier). This will provide a cushion of diskus doses in case the visit 3 date has to be moved further out for some reason. We want to avoid having to send out an extra Advair 250/50 diskus to bridge a short number of days between when their visit 2 Advair 250/50 diskus would run out and having their visit 3. Advair 250/50 diskus costs about \$310.
  - Set form as 'Unverified'
  - Click 'Save and Continue'
- If visit 3 is already scheduled, confirm date and time with participant
  - If date of appointment is changed, enter new date and time into 'Scheduled date and time'
  - Click 'Save and Continue'
- Note: Visit 3 will be via FaceTime if participant is qualified to continue in the study or the visit will be in the clinic if participant is not eligible to continue in the study.

#### 4.5. Visit 3 (Virtual Visit)

##### Overview

- Ensure participant meets criteria for continuation and treatment randomization
- Review questionnaires prior to FaceTime visit
- Conduct FaceTime Visit
- Do pre- and post-bronchodilator spirometry
- Do a random check of PEF values on participants EasyOne
  - Select a date for PEF value from "Peak Flow Report" in REDCap (note the date and PEF value)
- Randomize to study treatment

##### Time Frame

- Duration of V3: 1 hour

##### Equipment/materials

- iPad
- Coordinator EasyOne Spirometer (in case you need to show them anything via FaceTime)
- Visit 2 height and weight data (to compare with Visit 3)
- Latest data on Advair Diskus counter number from REDCap
- Latest data on ProAir counter number from REDCap
- Review all data (alerts, PEF, Diary card submissions, albuterol use, etc) in REDCap that affects whether or not the participant can be randomized to treatment. **Click here to see [How to View Participant Data](#) section in this MOP.**

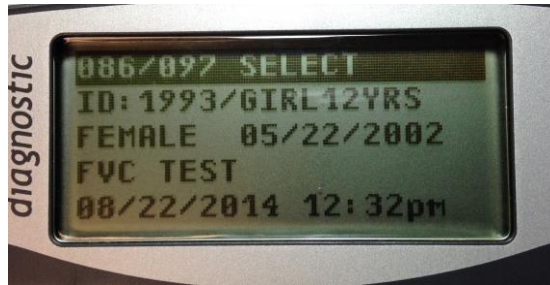
##### 4.5.1. Study Coordinator Procedures for Visit 3

- Prior to FaceTime, resolve any outstanding issues that would affect treatment randomization. **Click here to see [How to View Participant Data](#) section in this MOP.**
  - ACT scores at V1, V2, and V3  $\geq 20$
  - No unscheduled ED visits or hospitalizations **for asthma**
  - Rescue albuterol use less than 2.3 puffs per day average (less than 16 puffs per week excluding pre-medication for exercise). One nebulizer use is equivalent to 2

- puffs of beta-agonist. Cannot exceed more than 10 puffs per day on 2 consecutive days
- Completed 10 of the last 14 days of diary card entries (at least 1 entry per day)
  - Adherent with Advair 250/50 by taking at least 1 dose per day for 21 of the last 28 days
  - Review the completed CV form that the participant submitted for Visit 3
  - If there are any issues that have been discussed with Dr. Blake and an exception has been allowed, document the exception on the 'Protocol Exception' Form under the Ongoing column.
  - Ask participant for current height and weight
    - If height and weight have changed since V2, then you will need to do at least 1 effort before you can update the height and weight data
      - Changing height and weight data will change it for the present test and all subsequent tests
      - **Click here to see a summary of height data section in this MOP: [Height Data Summary in REDCap](#).**
  - EasyOne Spirometry – follow the instructions in the Coordinator EasyOne Manual (**Click this link to view the manual: [Manual for Coordinator EasyOne Instructions](#).**)
    - Document if it has not been 4 hours since the participant last used albuterol or Xopenex
    - Have participant do 3 pre-bronchodilator efforts.
    - Take picture of the flow volume curves using your iPad by holding down the power button at the same time as holding down the home key
      - These are saved to ensure we have data should the EasyOne get lost or broken
      - Save the photos on the shared drive at this location (**Click this link to see the location: [Folder for iPad Photos](#) )**
      - Use the following format for creating a folder name for file saving:  
**JAX102\JAX102V5\_07-10-14**
    - Record the PFT Data using the MICT PFT Worksheet. (**Click here to view the [PFT FaceTime Worksheet](#) )**
      - Ensure FEV1 is still  $\geq 70\%$  predicted using the predicted calculator found on the ACRC website at <https://www.jhcct.org/Secure/LASST/LASSTPFT.asp>
      - Calculate the % Predicted value as  

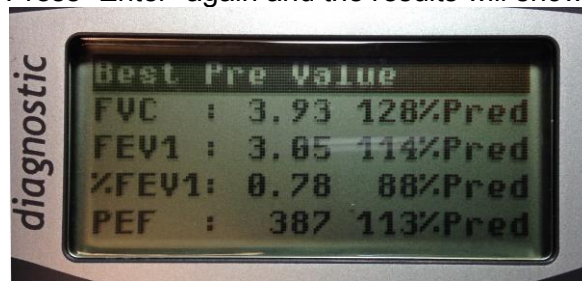
$$\% \text{ Predicted} = 100 * [\text{FEV1 (in Liters)} / \text{Predicted FEV1 (in Liters)}]$$
    - Have participant take 2 puffs of ProAir and wait 15 minutes
      - Can end FaceTime and restart in 15 minutes
    - Have participant do 3 post-bronchodilator efforts using same procedure as for pre-bronchodilator testing
  - Do a random check of PEF values on participants EasyOne
    - From the REDCap "Peak Flow Report", select 3 dates and write down the 3 PEF values for each of the 3 dates. Or you can print the Peak Flow Report. Do this when getting prepared for the FaceTime visit (you can do this a day or two before the visit date).
    - Instruct the participant turn on EasyOne
      - Go to "View Results" on EasyOne by pressing the right arrow key and pressing "Enter"
      - Use the right arrow button to tab to "Date"
      - Have the participant enter the first date you have selected and press "Enter"
      - Ask the participant to tell you the date on the screen; it will be under FVC Test (for example, 8/22/2014 in the image below)





○

- If the participant DID do the PEF, then the date on the screen will match the date you asked them to enter
- If the participant DID NOT actually do the PEF on the EasyOne on that date (even though they entered data on the Morning Report for that date, i.e. they made up numbers on the iPad Morning Report), the EasyOne will search for the closest date prior to the date you instructed the participant to enter.
- Press “Enter” again and the results will show up on the EasyOne screen



- - Ask the participant to tell you the PEF number (387 in the image above)
- Compare the 3 PEF values that were entered into REDCap with the PEF that is on the EasyOne. If they actually did the PEF on that date, then one of the 3 values in REDCAP will match with the value that they show on the EasyOne.
  - Note: Unfortunately, the EasyOne will only show you the PEF that is associated with the best sum of the FVC and FEV1 which is not always the highest PEF. But when you download all the data from the EasyOne, you can see every effort that that the participant made on the EasyOne for that date.
- Repeat the above for the other 2 dates (and 3 PEF values for each date) you selected from the REDCap data
- If the participant tells you that they don't have that date for any of the 3 dates viewed and the PEFs don't match up, then counsel the participant to enter only REAL values into the Morning Report.
  - Important for triggering their Asthma Action Plan to pop up on the iPad
  - Important for us to monitor their safety
- View counter on Advair Diskus and confirm that it is consistent with what is in REDCap
- View counter on ProAir and confirm that it is consistent with what is in REDCap
- Review any adverse effects, alerts, or any other issues
- Confirm Visit 4, Visit 5, and Visit 6 FaceTime date and time
- Confirm study medication shipping address and fedex delivery instructions
  - If there are any changes from previous visit, notify the Pharmacist (at WIL or ORL) or AC (for other sites)
- Remind participant to check emails every few days and 4 days before Visit 4 for the upcoming visit questionnaires
- Remind participant to have height and weight done before the Visit 4 FaceTime visit
- Chart in EPIC with a brief summary of visit

### 4.5.2. How to Conduct the Treatment Randomization

The treatment randomization will be conducted after confirming that the participant is eligible to be randomized at the FaceTime Visit 3 appointment. The online randomization should be completed after all V3 procedures (including questionnaires, review Diary Cards and lung function testing) have been performed.

- Go to the ALA-ACRC website at <http://cctrials.org/alaacrc/>
- Click on Information for Investigators
  - If prompted for login and password:
    - Login: alaacrc
    - Password: golst
- Click on MICT link shown below (you'll need to scroll down):

#### Current Protocol Pages

- APR (Asthma Patient Registry)
- SOYA (Study of Soy Isoflavones in Asthma)
- STAN (Study of Asthma and Nasal Steroids)
- LASST (Long-acting Beta Agonist Step Down Study)
- CPAP (Effect of Positive Airway Pressure on Reducing Airway Reactivity in Patients with Asthma)
- SCS (Smoking Cohort Study)
- MICT (Mobile Devices and the Internet to Streamline an Asthma Clinical Trial) [NCC Only]

- Type in User Name and Password
  - User Name: mictstaff
  - Password: mict4lasst!
- Select "TREATMENT Randomization" link as shown below:

**This page is just being assembled! More content coming soon!**

**Documents** (right-click on a link to save it as a file on your local computer)

#### Randomizations

TRIAL Randomization (MICT vs. LASST) [RZ stage 1]	<a href="#">Link</a>
TREATMENT Randomization (dose of ICS and/or LABA) [RZ stage 2]	<a href="#">Link</a>

- Type in User Name and Password (same as before)
- You will see this but click "Here" to login anyway

Login Failed

You Are Not Logged In To Our System

Click [Here](#) To Login

- Select Nemours as the clinic and enter your ALAACRC Pin and Password

ACRC Login

Clinic:	<input type="text" value="&lt;no selection&gt;"/>
PIN:	<input type="text"/>
Password:	<input type="password"/>
	<input type="button" value="Login"/> <input type="button" value="Reset"/>

- Complete the information and do the TREATMENT Randomization

Kathryn Blake, PharmD [NCC/K05] ([Logout](#))

### Participant Treatment Assignment

<b>Site</b>	
Clinical site:	<input checked="" type="radio"/> JAX <input type="radio"/> ORL <input type="radio"/> PNS <input type="radio"/> WIL
<b>Participant</b>	
Participant ID:	<input type="text"/>
<b>Confirmation</b>	
Re-enter participant ID:	<input type="text"/>
<b>User</b>	
Enter your name:	<input type="text"/>
PIN:	<input type="text" value="K05"/>
<b>Requirements</b>	
All TREATMENT eligibility requirements have been confirmed?	<input type="radio"/> (1) Yes <input type="radio"/> (2) No
<b>Action</b>	
Perform TREATMENT Assignment?	<input type="radio"/> (1) Yes <input type="radio"/> (2) No
<input type="button" value="Do Randomization"/> <input type="button" value="Cancel"/>	

- When you get the screen that shows the treatment randomization, print the file as a Microsoft XPS document. It won't actually print, you will save that document to your desktop and email it to the administrative coordinator, Stacey Gray ([Stacey.gray@nemours.org](mailto:Stacey.gray@nemours.org)). You don't need to actually print a hard copy or save it. You, as the coordinator, will immediately get an email verifying the treatment for the participant.
- The AC will open the file in adobe acrobat and save it as a pdf and save it in a folder on the S drive.

#### 4.5.3. Study Coordinator REDCap Instructions for Visit 3

Four days (3 nights) prior to the scheduled date, the participant will receive email messages with links to ACT, Children's Health Survey, EQ-5D, Quality of Life Questionnaires (if 15 yo or older) and Pre-Clinic Visit Survey and instructions to complete these at least 24 hours before their appointment.

In the MICT-data REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
- Review the following REDCap forms under Visit3-virtual
  - Asthma Control Test – participant version
    - The ACT status form has a notes field for your comments
  - Children's Health Survey – participant version
  - EQ-5D from the EuroQol Group
  - Quality of Life Questionnaires
    - If 15 yo or older when the consent was signed
    - This form has a notes field for your comments
  - Clinic Visit – participant version
    - This form has a notes field for your comments



- Click 'Save' on each form as comments are added

**After completing Visit 3 (FaceTime), SC should complete the following.**

In the MICT-data REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
- Click the button for 'Visit Dates' under Visit3-virtual
  - Complete the field for 'Actual visit date'
    - When a date is in this field, the Asthma Study Asthma Action Plan appears on the Trial website when the participant logs in and on the link (<https://apps.nemoursresearch.org/mict/admin/actionPlan.php>) used by study staff to print the Asthma Action Plan.
  - Set form as 'Complete'
  - Click 'Save'
- Click the button for 'Pulmonary Function Testing' under Visit3-virtual
  - Complete the fields as the information is collected.
    - During this process, you will go to <https://www.jhcct.org/Secure/LASST/LASSTPFT.asp>
  - Set form as 'Complete'
  - Click 'Save and go to Next Form'
- Go to the 'Asthma Study Asthma Action Plan' form if not already there.
  - Complete the fields as the information is collected.
  - You will need to go to <https://apps.nemoursresearch.org/mict/admin/baselinePEF.php> to have REDCap calculate the average PEF for the last 14 days. This link is on the Visit 3 Asthma Study Asthma Action Plan also. Please note that if the current day PEF is needed to have 10 PEF values from the last 14 days to meet the randomization eligibility criteria then the calculation from that link will not include the current day. This is because the data updates at 4AM each day. Therefore you will need to copy and paste the 9 available days into Excel, then get the day's current PEF and add it to Excel. Have Excel calculate the mean PEF for the 10 of the last 14 days of PEF data.
    - Some of the fields on this form are calculated.
  - Click 'Save and Continue'
  - NOTE: The 'Asthma Study Asthma Action Plan' form must be saved for the Asthma Study Action Plan to appear on the following link and on the Trial website when the participant logs in.
  - Follow the link to '<https://apps.nemoursresearch.org/mict/actionPlan/php>' to print the Asthma Study Asthma Action Plan for the participant on an 8.5x11 page. This printout can be mailed to the participant. A link to this web page ('Print Asthma Action Plan') is also available in the left sidebar under Project Bookmarks.
- Go to the 'Randomization form'.
  - Complete the fields in this form. This will include:
    - Reviewing clinic visit form (if prompted)
    - Reviewing diary card alerts
      - A summary of alerts can be viewed in the report 'data' in the REDCap project, MICT-alerts
      - Summary of diary card submission date and dose taken can be viewed with the tool at [https://apps.nemoursresearch.org/mict/admin/diary\\_submission.php](https://apps.nemoursresearch.org/mict/admin/diary_submission.php)
      - A summary of "urgent and unscheduled medical attention" alerts can be viewed as a report in the MICT-diary cards project and selecting "Questions

about urgent unscheduled medical attention” in the Reports section on the left side

- Set form as ‘Complete’
- Click ‘Save’
- Note: If any of the items on this form are checked, the participant does not meet criteria for “stable phase” and is NOT eligible to continue in the study. The run-in period must be extended or the participant must be removed from the study and come to the clinic to turn in their iPad and spirometer.
- Go to the ‘Study Information’ form under Ongoing in the grid
  - Complete the ‘Treatment arm field’
  - Set the form as ‘Complete’
  - Click ‘Save’
- Click the button for ‘Visit Dates’ under Visit4-virtual
  - Enter a date for ‘Target date’.
  - Enter a date and time into ‘Scheduled date and time’
  - Set form as ‘Unverified’
  - Click ‘Save’
- Click the button for ‘Visit Dates’ under Visit5-virtual
  - Enter a date for Target date
  - Set form as ‘Unverified’
  - Click ‘Save’
- Click the button for ‘Visit Dates’ under Visit6-virtual
  - Enter a date for Target date
  - Set form as ‘Unverified’
  - Click ‘Save’
- Click the button for ‘Visit Dates’ under Visit6-clinic
  - Enter a date for Target date
  - Set form as ‘Unverified’
  - Click ‘Save’

#### 4.5.4. RPh or Administrative Coordinator REDCap Instructions for Visit 3

**RPh or AC should do the following when visit 3 is complete.**

In the MICT-data REDCap project

- Click ‘Add/Edit Records’ and chose the participant ID for this participant
- Go to the ‘Drug Accountability Log’ form under Ongoing
  - Enter information in the following sections of this form
    - The next Diskus to be provided (which will be for the randomized treatment).
    - Click ‘Save Record’

Ship drug to participant

#### 4.6. Visit 4 (Virtual Visit)

##### Overview

- Ensure participant meets criteria for continuation
- Review questionnaires prior to FaceTime visit
- Conduct FaceTime Visit
- Do a random check of PEF values on participants EasyOne
  - Select a date for PEF value from “Peak Flow Report” in REDCap (note the date and PEF value)

##### Time Frame

- Target: 3 weeks after Randomization (V3)
- Window: 2 to 4 weeks after Randomization (V3)

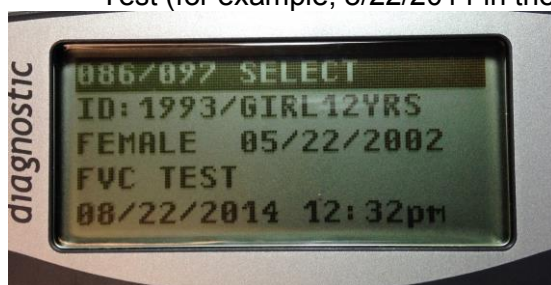
- Duration of V4: 1 hour

### Equipment/materials

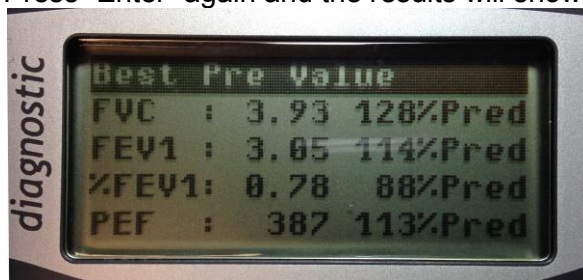
- iPad
- Coordinator EasyOne Spirometer (to check validity of PEFs participant has entered into Morning Reports and in case you need to show them anything via FaceTime)
- Visit 3 height and weight data (to compare with Visit 4)
- Latest data on Advair Diskus counter number from REDCap

#### 4.6.1. Study Coordinator Procedures for Visit 4.

- If there are any issues that have been discussed with Dr. Blake and an exception has been allowed, document the exception on the 'Protocol Exception' Form under the Ongoing column.
- Do a random check of PEF values on participants EasyOne
  - From the REDCap "Peak Flow Report", select 3 dates and write down the 3 PEF values for each of the 3 dates. Or you can print the Peak Flow Report. Do this when getting prepared for the FaceTime visit (you can do this a day or two before the visit date).
  - Instruct the participant turn on EasyOne
    - Go to "View Results" on EasyOne by pressing the right arrow key and pressing "Enter"
    - Use the right arrow button to tab to "Date"
    - Have the participant enter the first date you have selected and press "Enter"
    - Ask the participant to tell you the date on the screen; it will be under FVC Test (for example, 8/22/2014 in the image below)



- - If the participant DID do the PEF, then the date on the screen will match the date you asked them to enter
  - If the participant DID NOT actually do the PEF on the EasyOne on that date (even though they entered data on the Morning Report for that date, i.e. they made up numbers on the iPad Morning Report), the EasyOne will search for the closest date prior to the date you instructed the participant to enter.
- Press "Enter" again and the results will show up on the EasyOne screen



- - Ask the participant to tell you the PEF number (387 in the image above)
- Compare the 3 PEF values that were entered into REDCap with the PEF that is on the EasyOne. If they actually did the PEF on that date, then one of the 3 values in REDCAP will match with the value that they show on the EasyOne.

- Note: Unfortunately, the EasyOne will only show you the PEF that is associated with the best sum of the FVC and FEV1 which is not always the highest PEF. But when you download all the data from the EasyOne, you can see every effort that the participant made on the EasyOne for that date.
- Repeat the above for the other 2 dates (and 3 PEF values for each date) you selected from the REDCap data
- If the participant tells you that they don't have that date for any of the 3 dates viewed and the PEFs don't match up, then counsel the participant to enter only REAL values into the Morning Report.
  - Important for triggering their Asthma Action Plan to pop up on the iPad
  - Important for us to monitor their safety
- View counter on Advair Diskus and confirm that it is consistent with what is in REDCap
- Review any adverse effects, alerts, or any other issues
- Remind participant to
  - Use the Asthma Action Plan for symptom management
  - Contact primary asthma care doctor for asthma management issues
- Confirm Visit 5 FaceTime date and time
- Confirm study medication shipping address and fedex delivery instructions
  - If there are any changes from previous visit, notify the Pharmacist (at WIL or ORL) or AC (for other sites)
- Confirm study medication shipping address and fedex delivery instructions
  - If there are any changes from previous visit, notify the Pharmacist (at WIL or ORL) or AC (for other sites)
- Remind participant to check emails every few days and 4 days before Visit 3 for the upcoming visit questionnaires
- Remind participant to have height and weight done before the Visit 5 FaceTime visit
- Chart in EPIC with a brief summary of visit

#### 4.6.1. Study Coordinator REDCap Instructions for Visit 4

Three days prior to the scheduled date, the participant will receive email messages with links to the ACT and Pre-Clinic Visit Survey and instructions to complete these at least 24 hours before their appointment.

**Prior to visit 4**, SC should review participant's responses in the following forms: Asthma Control Test - participant version and Clinic Visit – participant version.

In the MICT-data REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
- Review the following REDCap forms under Visit4-virtual
  - Asthma Control Test – participant version
    - The ACT status form has a notes field for your comments
  - Clinic Visit – participant version
    - This form has a notes field for your comments
- Click 'Save' on each form as comments are added

**After completing Visit 4 (FaceTime), SC should complete the following.**

In the MICT-data REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
- Click the button for 'Visit Dates' under Visit4-virtual
  - Complete the field for 'Actual visit date'
  - Set form as 'Complete'
  - Click 'Save'
- Go to the 'Assessment for Treatment Failure'

- Complete the fields in this form. This will include:
  - Reviewing clinic visit form
  - Reviewing diary card alerts
    - A summary of alerts can be viewed in the report 'data' in the REDCap project, MICT-alerts
    - Summary of diary card submission date and dose taken can be viewed with the tool at [https://apps.nemoursresearch.org/mict/admin/diary\\_submission.php](https://apps.nemoursresearch.org/mict/admin/diary_submission.php)
    - A summary of "urgent and unscheduled medical attention" alerts can be viewed as a report in the MICT-diary cards project and selecting "Questions about urgent unscheduled medical attention" in the Reports section on the left side
- Set form as 'Complete'
- Click 'Save'
- Note: If the answer to any of the questions on this form is 'Yes', then the participant meets the criteria for treatment failure.
- Click the button for 'Visit Dates' under Visit5-virtual
  - If visit 5 is not scheduled :
    - Enter a date and time into 'Scheduled date and time'
    - Set form as 'Unverified'
    - Click 'Save'
  - If visit 5 is already scheduled, confirm date and time with participant
    - If date of appointment is changed, enter new date and time into 'Scheduled date and time'
    - Click 'Save'

#### 4.7. Visit 5 (Virtual Visit)

##### Overview

- Ensure participant meets criteria for continuation
- Review questionnaires prior to FaceTime visit
- Conduct FaceTime Visit
- Do pre- and post-bronchodilator spirometry
- Do a random check of PEF values on participants EasyOne
  - Select a date for PEF value from "Peak Flow Report" in REDCap (note the date and PEF value)
- Remind participant's parent to schedule follow up apt with PCP after Visit 6

##### Time Frame

- Target: 6 weeks after Randomization (V3)
- Window: 5 to 7 weeks after Randomization (V3)
- Duration of V5: 1 hour

##### Equipment/materials

- iPad
- Coordinator EasyOne Spirometer (in case you need to show them anything via FaceTime)
- Visit 4
- and weight data (to compare with Visit 5)
- Latest data on Advair Diskus counter number from REDCap

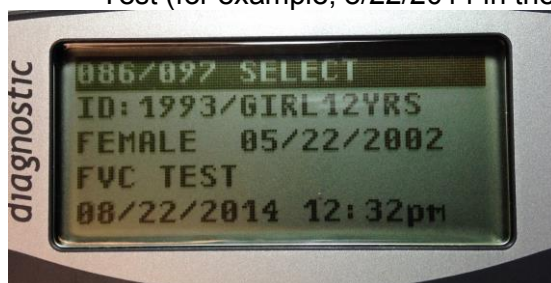
#### 4.7.1. Study Coordinator Procedures for Visit 5

- If there are any issues that have been discussed with Dr. Blake and an exception has been allowed, document the exception on the 'Protocol Exception' Form under the Ongoing

column.

- Ask participant for current height and weight
  - If height and weight have changed since V3, then you will need to do at least 1 effort before you can update the height and weight data
    - Changing height and weight data will change it for the present test and all subsequent tests
  - **Click here to see a summary of height data section in this MOP: [Height Data Summary in REDCap](#).**
- EasyOne Spirometry – follow the instructions in the Coordinator EasyOne Manual (**Click this link to view the manual: [Manual for Coordinator EasyOne Instructions](#).**)
  - Document if it has not been 4 hours since the participant last used albuterol or Xopenex
  - Have participant do 3 pre-bronchodilator efforts.
  - Take picture of the flow volume curves using your iPad by holding down the power button at the same time as holding down the home key
    - These are saved to ensure we have data should the EasyOne get lost or broken
    - Save the photos on the shared drive at this location (**Click this link to see the location: [Folder for iPad Photos](#).**)
    - Use the following format for creating a folder name for file saving:  
**JAX102\JAX102V5\_07-10-14**
  - Record the PFT Data using the MICT PFT Worksheet. (**Click here to view the [PFT FaceTime Worksheet](#).**)
    - Ensure FEV1 is still  $\geq 70\%$  predicted using the predicted calculator found on the ACRC website at <https://www.jhcct.org/Secure/LASST/LASSTPFT.asp>
    - Calculate the % Predicted value as  

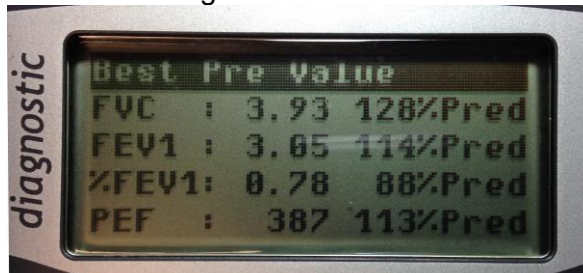
$$\% \text{ Predicted} = 100 * [\text{FEV1 (in Liters)} / \text{Predicted FEV1 (in Liters)}]$$
    - Have participant take 2 puffs of ProAir and wait 15 minutes
      - Can end FaceTime and restart in 15 minutes
    - Have participant do 3 post-bronchodilator efforts using same procedure as for pre-bronchodilator testing
    - Save the handwritten PFT Worksheet until the end of the study.
      - This worksheet will be needed in order to reconcile all the PFT data downloaded from the EasyOne device at Visit 6 with the data entered into REDCap.
- Do a random check of PEF values on participants EasyOne
  - From the REDCap “Peak Flow Report”, select 3 dates and write down the 3 PEF values for each of the 3 dates. Or you can print the Peak Flow Report. Do this when getting prepared for the FaceTime visit (you can do this a day or two before the visit date).
  - Instruct the participant turn on EasyOne
    - Go to “View Results” on EasyOne by pressing the right arrow key and pressing “Enter”
    - Use the right arrow button to tab to “Date”
    - Have the participant enter the first date you have selected and press “Enter”
    - Ask the participant to tell you the date on the screen; it will be under FVC Test (for example, 8/22/2014 in the image below)



○



- If the participant DID do the PEF, then the date on the screen will match the date you asked them to enter
- If the participant DID NOT actually do the PEF on the EasyOne on that date (even though they entered data on the Morning Report for that date, i.e. they made up numbers on the iPad Morning Report), the EasyOne will search for the closest date prior to the date you instructed the participant to enter.
- Press “Enter” again and the results will show up on the EasyOne screen



- - Ask the participant to tell you the PEF number (387 in the image above)
- Compare the 3 PEF values that were entered into REDCap with the PEF that is on the EasyOne. If they actually did the PEF on that date, then one of the 3 values in REDCAP will match with the value that they show on the EasyOne.
  - Note: Unfortunately, the EasyOne will only show you the PEF that is associated with the best sum of the FVC and FEV1 which is not always the highest PEF. But when you download all the data from the EasyOne, you can see every effort that that the participant made on the EasyOne for that date.
- Repeat the above for the other 2 dates (and 3 PEF values for each date) you selected from the REDCap data
- If the participant tells you that they don't have that date for any of the 3 dates viewed and the PEFs don't match up, then counsel the participant to enter only REAL values into the Morning Report.
  - Important for triggering their Asthma Action Plan to pop up on the iPad
  - Important for us to monitor their safety
- View counter on Advair Diskus and confirm that it is consistent with what is in REDCap
- Review any adverse effects, alerts, or any other issues
- Remind participant to
  - Use the Asthma Action Plan for symptom management
  - Contact primary asthma care doctor for asthma management issues
- Confirm Visit 6 FaceTime date and time
- Confirm study medication shipping address and fedex delivery instructions
  - If there are any changes from previous visit, notify the Pharmacist (at WIL or ORL) or AC (for other sites)
- Remind participant to check emails every few days and 4 days before Visit 3 for the upcoming visit questionnaires
- Remind participant to have height and weight done before the Visit 6 FaceTime visit
- Remind parent (may need to send to study email account if parent is not present) to schedule appointment with primary asthma care doctor for follow-up after Visit 6 (provide them with Visit 6 date so they know when to schedule).
- Chart in EPIC with a brief summary of visit

#### 4.7.2. Study Coordinator REDCap Instructions for Visit 5

Three days prior to the scheduled date, the participant will receive email messages with links to the ACT, Children's Health Survey, EQ-5D, Quality of Life Questionnaires (if 15 yo or older) and



Pre-Clinic Visit Survey and instructions to complete these at least 24 hours before their appointment.

**Prior to visit 5**, SC should review participant's responses in the following forms: Asthma Control Test - participant version, Children's Health Survey - participant version, Quality of Life Questionnaires and Clinic Visit – participant version.

In the MICT-data REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
- Review the following REDCap forms under Visit5-virtual
  - Asthma Control Test – participant version
    - The ACT status form has a notes field for your comments
  - Children's Heath Survey – participant version
  - EQ-5D from the EuroQol Group
  - Quality of Life Questionnaires
    - If 15 yo or older when the consent was signed
    - This form has a notes field for your comments
  - Clinic Visit – participant version
    - This form has a notes field for your comments
- Click 'Save' on each form if comments are added

**After completing Visit 5 (FaceTime), SC should complete the following.**

In the MICT-data REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
- Click the button for 'Visit Dates' under Visit5-virtual
  - Complete the field for 'Actual visit date'
  - Set form as 'Complete'
  - Click 'Save'
- Click the button for 'Pulmonary Function Testing' under Visit5-virtual
  - Complete the fields as the information is collected.
    - During this process, you will go to <https://www.jhcct.org/Secure/LASST/LASSTPFT.asp>
  - Set form as 'Complete'
  - Click 'Save'
- Go to the 'Assessment for Treatment Failure'
  - Complete the fields in this form. This will include:
    - Reviewing clinic visit form
    - Reviewing diary card alerts
      - A summary of alerts can be viewed in the report 'data' in the REDCap project, MICT-alerts
      - Summary of diary card submission date and dose taken can be viewed with the tool at [https://apps.nemoursresearch.org/mict/diary\\_submission.php](https://apps.nemoursresearch.org/mict/diary_submission.php)
      - A summary of "urgent and unscheduled medical attention" alerts can be viewed as a report in the MICT-diary cards project and selecting "Questions about urgent unscheduled medical attention" in the Reports section on the left side
  - Set form as 'Complete'
  - Click 'Save'
  - Note: If the answer to any of the questions on this form is 'Yes', then the participant meets the criteria for treatment failure.
- Click the button for 'Visit Dates' under Visit6-virtual

- If visit 6 is not scheduled :
  - Enter a date and time into 'Scheduled date and time'
  - Set form as 'Unverified'
  - Click 'Save'
- If visit 5 is already scheduled, confirm date and time with participant
  - If date of appointment is changed, enter new date and time into 'Scheduled date and time'
  - Click 'Save'

#### 4.8. Visit 6 – Part 1 (Virtual Visit)

##### Overview

- WebEx with SC, Parent, Participant to conduct the Research Participant Assessment Interview
- Review questionnaires prior to FaceTime visit
- Conduct FaceTime Visit
- Do pre- and post-bronchodilator spirometry
- Do a random check of PEF values on participants EasyOne
  - Select a date for PEF value from "Peak Flow Report" in REDCap (note the date and PEF value)
- Conduct the onsite clinic visit

##### Time Frame

- Target: 12 weeks after Randomization (V3)
- Window: 11 to 13 weeks after Randomization (V3)
- Duration of V6: 1 hour for Part 1; 1 hour for Part 2

##### Equipment/materials

- Computer access
- Internet / Phone access
- Equipment/materials for recording Research Assessment Interview
- Forms (**Click this link to view the forms: [Research Assessment interview forms.](#)**)
  - RESEARCH ASSESSMENT FORM – Female
  - RESEARCH ASSESSMENT FORM – Male
- iPad
- Coordinator EasyOne Spirometer (in case you need to show them anything via FaceTime)
- Visit 5 height and weight data (to compare with Visit 6)
- Latest data on Advair Diskus counter number from REDCap

#### 4.8.1. Study Coordinator Procedures for Visit 6 – Part 1

##### Webex Research Assessment Interview

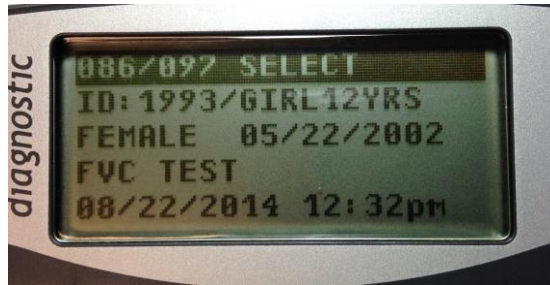
- Contact parent and participant by phone using WebEx Meeting Center per Audio Recording Protocol instructions. (**Click this link to see MOP: [MICT Audio Recording MOP.](#)**)
  - **IMPORTANT:** The same parent who completes the Research Assessment interview with the study coordinator at this visit, MUST be the same person at Visit 6. Please inform the family of this – you will also enter this information REDCap to help you remember when it is time to do the Visit 6 Research Assessment interview.
- Administer the Research Assessment form. **To avoid missing any questions, make a check mark after each question is asked.** (**Click this link to view the forms: [Research Assessment interview forms.](#)**)
  - RESEARCH ASSESSMENT FORM – Female
  - RESEARCH ASSESSMENT FORM – Male

- Note: you do NOT need to conduct the Newest Vital Sign Assessment
- After completing the WebEx, disconnect the call and then begin the FaceTime portion of the visit

### FaceTime Visit

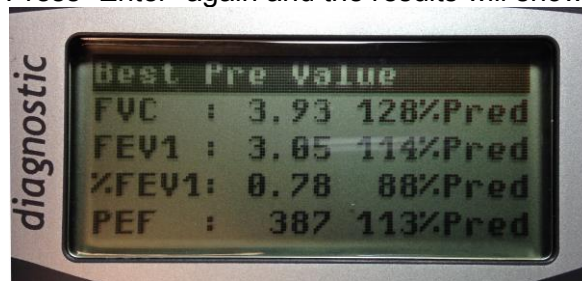
- If there are any issues that have been discussed with Dr. Blake and an exception has been allowed, document the exception on the 'Protocol Exception' Form under the Ongoing column.
- Ask participant for current height and weight
  - If height and weight have changed since V5, then you will need to do at least 1 effort before you can update the height and weight data
    - Changing height and weight data will change it for the present test and all subsequent tests
    - **Click here to see a summary of height data section in this MOP:** [Height Data Summary in REDCap](#).
- EasyOne Spirometry – follow the instructions in the Coordinator EasyOne Manual (**Click this link to view the manual:** [Manual for Coordinator EasyOne Instructions](#).)
  - Document if it has not been 4 hours since the participant last used albuterol or Xopenex
  - Have participant do 3 pre-bronchodilator efforts.
  - Take picture of the flow volume curves using your iPad by holding down the power button at the same time as holding down the home key
    - These are saved to ensure we have data should the EasyOne get lost or broken
    - Save the photos on the shared drive at this location (**Click this link to see the location:** [Folder for iPad Photos](#).)
  - Use the following format for creating a folder name for file saving:  
**JAX102\JAX102V5\_07-10-14**
  - Record the PFT Data using the MICT PFT Worksheet. (**Click here to view the** [PFT FaceTime Worksheet](#).)
    - Ensure FEV1 is still  $\geq 70\%$  predicted using the predicted calculator found on the ACRC website at <https://www.jhcct.org/Secure/LASST/LASSTPFT.asp>
    - Calculate the % Predicted value as  

$$\% \text{ Predicted} = 100 * [\text{FEV1 (in Liters)} / \text{Predicted FEV1 (in Liters)}]$$
    - Have participant take 2 puffs of ProAir and wait 15 minutes
      - Can end FaceTime and restart in 15 minutes
    - Have participant do 3 post-bronchodilator efforts using same procedure as for pre-bronchodilator testing
    - Save the handwritten PFT Worksheet until the end of the study.
      - This worksheet will be needed in order to reconcile all the PFT data downloaded from the EasyOne device at Visit 6 with the data entered into REDCap.
- Do a random check of PEF values on participants EasyOne
  - From the REDCap "Peak Flow Report", select 3 dates and write down the 3 PEF values for each of the 3 dates. Or you can print the Peak Flow Report. Do this when getting prepared for the FaceTime visit (you can do this a day or two before the visit date).
  - Instruct the participant turn on EasyOne
    - Go to "View Results" on EasyOne by pressing the right arrow key and pressing "Enter"
    - Use the right arrow button to tab to "Date"
    - Have the participant enter the first date you have selected and press "Enter"
    - Ask the participant to tell you the date on the screen; it will be under FVC Test (for example, 8/22/2014 in the image below)



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- If the participant DID do the PEF, then the date on the screen will match the date you asked them to enter
- If the participant DID NOT actually do the PEF on the EasyOne on that date (even though they entered data on the Morning Report for that date, i.e. they made up numbers on the iPad Morning Report), the EasyOne will search for the closest date prior to the date you instructed the participant to enter.
- Press “Enter” again and the results will show up on the EasyOne screen



- - Ask the participant to tell you the PEF number (387 in the image above)
- Compare the 3 PEF values that were entered into REDCap with the PEF that is on the EasyOne. If they actually did the PEF on that date, then one of the 3 values in REDCAP will match with the value that they show on the EasyOne.
  - Note: Unfortunately, the EasyOne will only show you the PEF that is associated with the best sum of the FVC and FEV1 which is not always the highest PEF. But when you download all the data from the EasyOne, you can see every effort that that the participant made on the EasyOne for that date.
- Repeat the above for the other 2 dates (and 3 PEF values for each date) you selected from the REDCap data
- If the participant tells you that they don't have that date for any of the 3 dates viewed and the PEFs don't match up, then counsel the participant to enter only REAL values into the Morning Report.
  - Important for triggering their Asthma Action Plan to pop up on the iPad
  - Important for us to monitor their safety
- View counter on Advair Diskus and confirm that it is consistent with what is in REDCap
- Review any adverse effects, alerts, or any other issues
- Remind participant to
  - Use the Asthma Action Plan for symptom management
  - Contact primary asthma care doctor for asthma management issues
- Confirm Visit 6 Clinic Visit date and time
  - The Visit 6 Clinic Visit should be within 7 days of the Visit 6 FaceTime visit
- Remind participant to bring all used and unused study drug (ProAir, all Diskuses), EasyOne and EasyOne stand, HotSpot if they used one during the study, and iPad to the clinic visit. We will delete study information from the iPad at the clinic visit.
- Chart in EPIC with a brief summary of visit

#### 4.8.2. Study Coordinator REDCap Instructions for Visit 6 – Part 1

Four days prior to the scheduled date, the participant will receive email messages with links to the ACT, EQ-5D, Children's Health Survey, Quality of Life Questionnaires (if 15 yrs or older) and Pre-Clinic Visit Survey and instructions to complete these at least 24 hours before their appointment.

**Prior to visit 6-virtual**, SC should review participant's responses in the following forms: Asthma Control Test - participant version, Children's Health Survey - participant version, Quality of Life Questionnaires and Clinic Visit – participant version.

In the MICT-data REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
- Review the following REDCap forms under Visit 6-virtual
  - Asthma Control Test – participant version
    - The ACT status form has a notes field for your comments
  - Children's Heath Survey – participant version
  - EQ-5D from the EuroQol Group
  - Quality of Life Questionnaires
    - If 15 yo or older when the consent was signed
    - This form has a notes field for your comments
  - Clinic Visit – participant version
    - This form has a notes field for your comments
- Click 'Save' on each form if comments are added

**After completing Visit 6 (FaceTime), SC should complete the following.**

In the MICT-data REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
- Click the button for 'Visit Dates' under Visit6-virtual
  - Complete the field for 'Actual visit date'
  - Set form as 'Complete'
  - Click 'Save Record'
- Click the button for 'Research Assessment Interview' form under Visit 6-virtual
  - Complete the Research Assessment Interview form
  - A PDF file with the questions to ask participants is available in this REDCap form.
  - Set form as 'Complete' . .
  - Click 'Save Record'
- Click the button for 'Pulmonary Function Testing' under Visit6-virtual
  - Complete the fields as the information is collected.
    - During this process, you will go to <https://www.jhcct.org/Secure/LASST/LASSTPFT.asp>
  - Set form as 'Complete'
  - Click 'Save'
- Go to the 'Assessment for Treatment Failure'
  - Complete the fields in this form. This will include:
    - Reviewing clinic visit form
    - Reviewing diary card alerts
      - A summary of alerts can be viewed in the report 'data' in the REDCap project, MICT-alerts
      - Summary of diary card submission date and dose taken can be viewed with the tool at [https://apps.nemoursresearch.org/mict/admin/diary\\_submission.php](https://apps.nemoursresearch.org/mict/admin/diary_submission.php)
      - A summary of "urgent and unscheduled medical attention" alerts can be viewed as a report in the

MICT-diary cards project and selecting “Questions about urgent unscheduled medical attention” in the Reports section on the left side

- Set form as ‘Complete’
- Click ‘Save’
- Note: If the answer to any of the questions on this form is ‘Yes’, then the participant meets the criteria for treatment failure.
- Click the button for ‘Visit Dates’ under Visit6-clinic
  - If the clinic portion of visit 6 is not scheduled :
    - Enter a date and time into ‘Scheduled date and time’
    - Set form as ‘Unverified’
    - Click ‘Save’
  - If the clinic portion of visit 6 is already scheduled, confirm date and time with participant
    - If date of appointment is changed, enter new date and time into ‘Scheduled date and time’
    - Click ‘Save’

#### 4.9. Visit 6 – Part 2 (Clinic Visit)

##### Overview

- Conduct Visit 6 procedures
- Retrieve study medications and EasyOne
- Blood draw for DNA and Phadiatop
- Prepare iPad to give to participant
- End of study satisfaction surveys for parent and child

##### Time Frame

- Target: 7 days after Visit 6 – Part 1 (Virtual)
- Duration of V1: 1 hour

##### Equipment/materials

- NIOX MINO (for sites conducting exhaled nitric oxide procedure)
- Coordinator’s iPad so physician can complete physical exam in REDCap

##### Procedures Overview:

- Confirm participant’s and parent’s email addresses
- Physical Exam including height and weight
- Measure exhaled nitric oxide (eNO). This must be completed before pulmonary function testing (if applicable for your site)
- Blood draw for DNA and Phadiatop, processing, storage/shipment
- Retrieve all used and unused study drug (ProAir, all Diskuses), EasyOne and EasyOne stand
- Download and reconcile EasyOne data with PFT data in REDCap
- Send the Physician Study Closure Letter to primary asthma physician. (**Click this link to see IRB approved letters to participant Physicians: [Physician Letters](#)**). Include copy of spirometry results
- Chart in EPIC with a brief summary of visit

#### 4.9.1. Study Coordinator Procedures for Visit 6 – Part 2

##### 4.9.1.1. Email Addresses

- Email invitations with links to the End of Study Satisfaction Survey will be sent the day after Visit6-Clinic to both the parent and participant.
- Confirm the participant’s and parent’s email addresses that we have in REDCap for these



messages.

- Parent and Participant may choose to use the same email address.
- They may continue to use the study gmail account if they desire.
- **Click here to see [SC REDCap Instructions for Visit 6](#) section in this MOP)**

#### 4.9.1.2. Exhaled Nitric Oxide

- Collect exhaled nitric oxide results (if your site is collecting exhaled nitric oxide)
- Record data in REDCap (**Click here to see [SC REDCap Instructions for Visit 6](#) section in this MOP).**

#### 4.9.1.3. Physical Exam

- Have physical exam done
- Record data in REDCap (**Click here to see [SC REDCap Instructions for Visit 6](#) section in this MOP).**
  - The physician will need to log into their REDCap account to complete the form, electronically sign, and lock the form

#### 4.9.1.4. Collect Study Medication

- Collect all study medication and return to pharmacist (ORL and WIL) or document receipt in REDCap (**Click here to see [SC REDCap Instructions for Visit 6](#) section in this MOP).**

#### 4.9.1.5. Collect the EasyOne Spirometer and Download/Reconcile Results

- Put the EasyOne into the cradle
  - Download all study records
    - After the study is over, the SC will need to reconcile the PFT results (FVC, FEV1, and PEF) with the data that was entered into REDCap during the FaceTime visits.
    - To reconcile the data, the SC will need to view the PFTs collected at FaceTime V2, V3, V4, V5, and V6 downloaded from the EasyOne (this won't be much fun).
      - If the REDCap data are different from the EasyOne data, the SC will need to correct the Pulmonary Function Testing form in REDCap
        - Add a comment for any correction made
  - Print 3 copies of the Visit 6 results (for primary care physician, participant copy, and for site records)

#### 4.9.1.6. Collect Blood Specimens

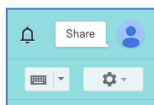
- **Click here to see [Blood Collection and Processing for DNA, plasma and serum](#) section in this MOP.**

#### 4.9.1.7. Preparing iPad to give to Participant for Keeps

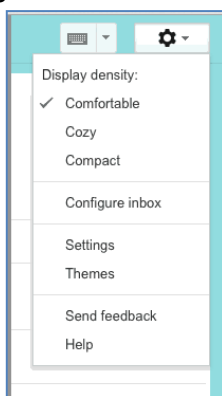
- Remove the shortcut to the MICT website
  - Touch and hold until you get an "X" on the icon, and then touch "X" to delete
- Remove the shortcut to the morning diary report
  - Touch and hold until you get an "X" on the icon, and then touch "X" to delete
- Remove the shortcut to the evening diary report
  - Touch and hold until you get an "X" on the icon, and then touch "X" to delete
- Open FaceTime
  - Remove all study-related contacts (your name and any other coordinator's name that is in their list of contacts)
- Open the Videos app and delete the study-related help videos (these are just the instructional videos we put in the iPad for the participants)
  - FaceTime video
  - Hotspot video



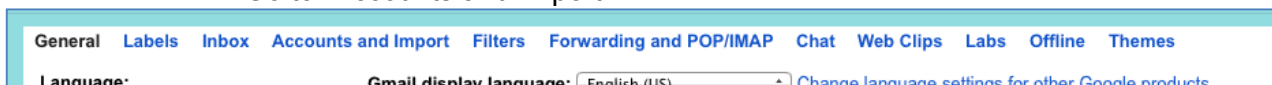
- EasyOne video
- Discus Inhaler video
- MDI inhaler video
- Open the iBooks app
  - Delete the EasyOne Participant Instructions pdf document
- Gmail
  - Have the participant log into their study gmail account to have them change their recovery email
    - Click on the gear icon in the upper right corner (below the blue person icon)



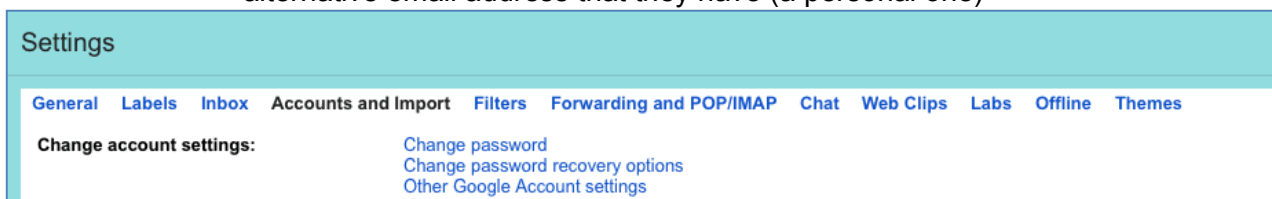
- Go to “Settings”



- Go to “Accounts and Import”



- Go to “Change password and recovery options” and have them put in any alternative email address that they have (a personal one)



#### 4.9.2. Study Coordinator REDCap Instructions for Visit 6 – Part 2

##### SC REDCap Steps in Preparation for Visit 6 – Part 1 (Clinic Visit)

In the **MICT-equipment** REDCap project

- Go to ‘Data Search’ in the middle of the page

**Data Search**

<b>Choose a field to search</b> <small>(excludes multiple choice fields)</small>	<div style="border: 1px solid #ccc; padding: 2px; display: flex; align-items: center;"> <span style="margin-right: 10px;">-- select search field --</span> <span style="font-size: 10px;">▼</span> </div>
<b>Search query</b> <small>Begin typing to search the project data, then click an item in the list to navigate to that record.</small>	<div style="border: 1px solid #ccc; height: 20px; width: 100%;"></div>

- In 'Choose a field to search', select 'Participant ID'

The screenshot shows a dropdown menu for selecting a search field. The options are:

- select search field --
- name (Name This will be used for iPad name, iTunes account, gmail a...)
- pin (PIN for iPadThis is generated by adding 1234 to the number port...)
- ipad\_serial (iPad serial number)
- ✓ participant\_id (Participant ID)

- In the 'Search Query' box, enter the 'Participant ID' (e.g. JAX163, PNS114)
- Click 'Tracking Information' in left side panel under Data Collection.
- Check for equipment that was given to participant that needs to be returned.
  - EasyOne spirometer
  - Hotspot serial number if they received one

### Physician *REDCap* Steps During Visit 6

#### To Complete the Physical Exam:

Log into REDCap

In the MICT-data REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
- Click the button for 'Physical Exam' under Visit6-clinic
- Complete the fields in this form as the exam is performed.
- Set the form as 'Complete'
- Check the 'Lock' and 'E-signature' options.
- Click Save 'Record'

Log out of REDCap

Notes: Any physician with a REDCap username and access to the REDCap project can e-sign the Physical Exam form of any participant at any time. E-signing in REDCap consists of checking the boxes next to 'Lock' and 'E-signature' and saving the record. The status of the form can be set to 'Incomplete', 'Unverified' or 'Complete' when the form is e-signed and the status is locked along with the other fields on the form. Once a form is e-signed, it must be unlocked before any changes can be made.

Only REDCap users who have the user right to lock and e-sign a form can see the check boxes for locking and e-signing the form. Forms that are locked and e-signed will have a padlock and green shield (with check) in the event grid. Also, forms that are locked and e-signed will not have buttons for saving the form at the bottom of the page when viewing the form.

Study coordinators can change the status of the Physical Exam form before the form is e-signed.

If a physician does not have REDCap access yet:

- Go to the 'Physical Exam' form if not already there. Print blank form. SC to complete demographic and vital sign information by hand. Physician will complete the exam portion and print and sign in designated areas. The SC will then enter the data into the form in REDCap.
  - Complete the fields
  - Set form as 'Complete'
  - Click 'Save and go to Next Form'

**After completing Visit 6 – Part 2 (Clinic Visit), SC should complete the following.**

In the MICT-data REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
- Click the button for 'Participant Info' under Ongoing
  - Check the 'Participant's email address'
    - If the participant will continue to use the study gmail address, this may be entered in the field 'Participant's email address'.
    - If the participant will not have his/her own email address, insert the parent's email address in the field 'Participant's email address' if the participant does not want to use the study gmail address
  - Check the 'Parent's email address'
    - If the parent wishes to continue using the study gmail address, this may be used. Enter the study gmail address into the field 'parent/guardian's email-address'.
      - The parent's personal email will still be visible by clicking the history icon (the H in a circle).
- Click the button for 'Visit Dates' under Visit6-clinic
  - Complete the field for 'Actual visit date' (must do this in order for the End of Study Satisfaction Survey's to be sent at 4AM the next day).
  - Set form as 'Complete'
  - Click 'Save'
- The day after the 'Actual visit date', email invitations will be sent to the participant's and the parent's email addresses for the End of Study Satisfaction Surveys. [AsthmaResearch@nemours.org](mailto:AsthmaResearch@nemours.org) will receive a copy of these messages. If the 'Actual visit date' is not saved the day the visit takes place or if the participant finished the study previously, the email invitations will not be sent automatically. ***Click here to see how to manually 'send email invitations to a participant or parent for the End of Study Satisfaction Survey' section in this MOP: Missing and/or Re-sending Questionnaires to Participants.***
  - After a survey is **completed** it gets a green check in the list of instruments in the left side bar and the Event grid
  - The survey invitations for these surveys are sent the day after the 'actual visit date' for visit 6-clinic by computer code that is outside of REDCap. This means that these messages will not be listed in REDCap's survey invitation log. The invitation for the parent is sent to the address stored in the parent's email address field. The invitation for the participant is sent to the address stored in the participant's email address field.
- After collecting specimen, go to the 'Specimen Collection' form
  - Indicate the samples that were collected and scan in barcodes
  - Set form as 'Complete'
  - Click 'Save'
- Go to the 'Nitric Oxide' form if not already there
  - Complete the fields as the information is collected.
  - Set form as 'Complete'
  - Click 'Save Record'
- Go to the 'Drug Accountability Log' form under Ongoing
  - Record information about returned inhalers and Diskus
  - Set form as 'Complete'
  - Click 'Save and go to Next Form'
- Go to the 'Treatment Termination' form under Ongoing if not already there
  - Complete this form
  - Set form as 'Complete'
  - Click 'Save Record'

NOTE: When the field 'Type of termination' is completed, the participant will not be able to log in to the Trial website or submit diary reports.

In the MICT-equipment REDCap project

- Click 'Summary' report under 'Reports' in the left side panel

- Click on the username for this participant
  - This will take you to the 'Name' form
  - Set form as 'Complete' if it isn't already
  - Click 'Save and go to Next Form'
- Go to the 'Tracking' form if not already there
  - Set 'Username is:' to 'Complete – iPad permanently given to participant'
  - Enter date EasyOne was returned
  - Enter date hotspot was returned, if appropriate
  - Set form as 'Complete'
  - Click 'Save Record'

### 4.9.3. Administrative Coordinator REDCap Instructions for Visit 6 – Part 2

#### **Administrative Coordinator (AC) Tasks**

**After completing Visit 6 – Part 2 (Clinic Visit), AC should complete the following.**

When \$25 is added to participant's CTPayer account. Record this REDCap.

In the MICT – DC summary REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
  - CTPayer account number can be viewed in 'Participant Information' form
- Click the button for 'Clinic Visits, FaceTime Visits, Satisfaction Survey'
- Record whether credit was added to card and date this was done
- Click 'Save Record'

In the MICT-equipment REDCap project

- Click 'Add/Edit Records' and chose the username assigned this participant
- Click 'Tracking Information' in left side panel under Data Collection.
- Enter data for the following fields
  - Set 'Username is:' to 'Complete-iPad permanently given to participant'
  - Date EasyOne was returned
  - If appropriate, date hotspot was returned
- Set the form as 'Complete'
- Click 'Save Record'

In the MICT-web info REDCap project

- Click 'Add/Edit Records' and chose the username assigned to this participant
- Go to the 'Basics' form if not already there, using the left side panel
- Set the form as 'Complete'
- Click 'Save Record'

**After participant and parent complete the End of Study Satisfaction Surveys, record sending compensation.**

In the MICT – DC summary REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
  - CTPayer account number can be viewed in 'Participant Information' form
- Click the button for 'Clinic Visits, FaceTime Visits, Satisfaction Survey'
- Record when credit was added to form and date this was done
- Record that Walmart card was sent and date this was done
- Click 'Save Record'

## 5. Screen Failures Between V1 to V3

### 5.1. Overview

- To identify participants who have met the criteria for screen failure during the open-label stable phase of the study (Visit 1 up to Visit 3)

- To identify participants who are interested in being rescreened and begin the processes for rescreening

## 5.2. Screen failure at V1

- At Visit 1, the main criteria that would be unexpected is an ACT <20 or FEV1 <70% of predicted. All the other criteria should have been assessed by the SC using the Screening form and Baseline Asthma and Medical History form.

### 5.2.1. Study Coordinator REDCap Steps for Participant who Failed at Visit 1

In the MICT-data REDCap project, SC should:

- Click 'Add/Edit Records' and choose the participant ID for this participant
- Go to the 'Treatment Termination' form under Ongoing in the grid
  - Complete this form
  - Set form as 'Unverified' (Collection of Diskuses will be recorded when participant comes in to clinic to return equipment.)
  - Click 'Save Record'

NOTE: When the field 'Type of termination' is completed, the participant will not be able to log in to the Trial website or submit diary reports. This will also prevent any alerts from being generated.

## 5.3. Determining if the Participant has Failed Between V1 to V3

- At Visit 1, review the 'Assessment for Stable Phase' form (under the Visit 2 forms in REDCap) to determine if a participant must discontinue the study (they may be interested in being rescreened in 4 weeks)
  - At Visit 1, the main criteria that would be unexpected is an ACT <20 or FEV1 <70% of predicted. All the other criteria should have been assessed by the SC using the Screening form and Baseline Asthma and Medical History form.
- At Visit 2, review the 'Assessment for Stable Phase' form (under the Visit 2 forms in REDCap) to determine if a participant must discontinue the study (they may be interested in being rescreened in 4 weeks)
- At anytime between Visit 1 and Visit 3, a participant may meet the criteria for screen failure
  - Use the 'Assessment for Stable Phase' under Visit 2 to review criteria
    - SC may have received alerts that some these criteria (corticosteroid use, unscheduled visits, excessive albuterol use) may have been met
      - Contact the PI, Dr. Blake, with questions if there are issues related to asthma stability and whether or not the participant can continue in the study. This will be handled on a participant by participant basis with consultation with the study physician
- If the participant meets the criteria for screen failure
  - They may keep the iPad (for now), **if** the SC is **very** confident that they will continue with the study and be re-screened, otherwise, schedule an appointment for the participant to return the iPad, EasyOne Plus, study medication
    - Ensure that the participant has some personal controller medication (required for the study) and rescue medication to use until they can be rescreened.

## 5.4. Study Coordinator Procedures for Screen Failures at Visit 2 or Visit 3

- Complete procedures, forms and questionnaires for the visit
- Complete steps required in REDCap (this will stop all alerts as well)
- DO NOT delete any data from the forms in REDCap
- After 4 weeks the participant may be rescreened as a new participant

## 5.5. REDCap Steps for Ending Participation at Visit 2 or Visit 3

### 5.5.1. REDCap Steps for Participant who Failed Stable Phase but will be Rescreened

These steps should be performed for any participant who has completed visit 1 and not completed visit 3. (This can be before or after visit 2.)

#### **Study Coordinator (SC) Tasks**

In the MICT-data REDCap project, SC should:

- Click 'Add/Edit Records' and choose the participant ID for this participant
- Go to the 'Treatment Termination' form under Ongoing in the grid
  - Complete this form
  - Set form as 'Unverified' (Collection of Diskuses will be recorded when participant comes in to clinic to return equipment.)
  - Click 'Save Record'

NOTE: When the field 'Type of termination' is completed, the participant will not be able to log in to the Trial website or submit diary reports. This will also prevent any alerts from being generated.

When the participant is in the clinic, the old Diskus will be collected and equipment (iPad, spirometer, Hotspot) will be returned, **do the following in REDCap**:

In the MICT-equipment RedCap project, AC should:

- Click 'Add/Edit Records' and choose the username assigned to this participant
- Click 'Tracking Information' in left side panel under Data Collection.
  - Record any equipment returns that occurred.
- Click 'Save Record'

#### **Study Coordinator (SC) Tasks when the participant comes to the clinic**

In the MICT-data REDCap project, SC should

- Click 'Add/Edit Records' and choose the participant ID for this participant
- Go to the 'Drug Accountability Log' form under Ongoing
  - Record the date for all the Diskus that were returned
  - Set form as 'Complete'
  - Click 'Save and go to Next Form'
- Go to the 'Treatment Termination' form if not already there
  - Finish completing this form
  - Set form as 'Complete'
  - Click 'Save Record'

## 5.6. Study Coordinator Procedures for Re-screening a Participant at Visit 1

### **Overview**

- Follow all the same procedures as for the original Visit 1 but you **do not** need to repeat the Webex to conduct the Research Assessment interview
  - You will do the Research Assessment Interview at Visit 6
    - The Visit 6 Research Assessment interview is assessing how much they retained about the study while participating from V1 to V6.

### **SC Procedures**

Refer to steps for Visit 1 (*Click here to see [Screening Steps](#) and [Visit 1 - Part 2 Steps](#) sections in this MOP*).

## 5.7. REDCap Step for Rescreening a Participant

### **Overview**

- The participant will be given an new Participant ID, which will be based on their original ID
  - If the original was JAX102, the new will be JAX102a
- The participant will continue to use the same login username and password (the password

that they created) they used before being placed on hold

### **Administrative Coordinator (AC) Tasks**

In the MICT-web info REDCap project

- Click 'Add/Edit Records' and chose the username for the participant
- Go to the 'Basics' form if not already there, using the left side panel
- Enter the new 'Participant ID'
  - This will be the old Participant ID with an 'a' added to the end.
  - If an 'a' has already been added, replace it with a 'b'.
  - The first three letters of the participant ID must be uppercase and the letter added to the end must be lowercase, i.e. JAX101a.
- Click 'Save Record'

In the MICT-data REDCap project

- Click 'Add/Edit Records', chose Arm1:MICT, type the new Participant ID and select 'Enter'
  - This should be the same as the participant ID that was entered into MICT-web info in the steps above.
  - The first three letters of the participant ID must be uppercase and the letter added to the end must be lowercase, i.e. JAX101a
- Go to the 'Patient Screening Log' form and enter data
  - 3 fields in this form may be left blank initially, these are
    - Main reason failed screen or not enrolled
    - Successfully completed V1 (enrolled)
  - Set form status as 'unverified'
  - Click 'Save Record'
- Go to the 'Study Information' form
  - Enter data into all but 'Treatment arm'
    - Be sure to answer 'Yes' for 'Is this record for a rescreen?'
    - The field 'Additional email address for alert messages' should be completed if a SC from a site other than the one indicated in the form will be following the participant. Otherwise, the field can be left blank.
  - Set form status as 'Unverified'
  - Click 'Save and go to Next Form'
- Go to the 'Participant Information form'
  - Enter data for all fields
  - It is critical that the following fields are completed as some functions depend on the data
    - Participant's first and last name
    - Study email address
    - Parent/guardian's email address
    - Physician's first name
    - Physician's last name
    - Physician's phone number
  - Set form as 'Complete' (or 'Unverified' if data entry is not completed)
  - Click 'Save Record'
- Go to the 'Signed Consent' form
  - Enter 'Yes' for "Successfully completed consent process"
    - When this is saved, email messages will be NOT be sent if 'Yes' has been saved for 'Is this record for a rescreen?' in the 'Study Information' form:
      - Screening form under Screening
      - Reminder with gmail account information



- Enter date consent was signed.
- Enter participant's age on the date the consent was signed
- Set form status as 'Complete'
- Click 'Save Record'
- NOTE.
- 
- Go to the 'Visit Dates' form under Screening
  - These fields are for the Consenting Phone Visit. Because this is not being repeated, these field should be left blank
  - Enter a note that Consenting Phone Visit information is stored under Participant ID X. (and enter ID in place of X)
  - Set form status as 'Complete'
  - Click 'Save Record'
- Go to the 'Visit Dates' form under Visit 1
  - If visit 1 has not been scheduled yet, skip this section and complete this section later
  - If visit 1 has been scheduled, enter data for the following fields
    - Target date
    - Scheduled date and time
      - An email reminder with gmail account information will be automatically sent to the parent's email address when the scheduled visit date is within 6 days.
      - Email invitations for the surveys to be completed before visit 1 will automatically be sent when the scheduled visit date is within 4 days
  - Leave the field 'Is the scheduled visit date within 4 days?' blank unless you want email messages with links to surveys for visit 1 to be sent immediately.
  - Set form status as 'Unverified'
  - Click 'Save Record'
  - If visit 1 has been scheduled, also enter target dates under Visit2-virtual and Visit3-virtual, set each form status to 'Unverified' and click 'Save Record'.
    - These target dates are necessary for the functions that display the Asthma Action Plan
- Go to the 'Research Assessment Interview' form under Visit1
  - Complete this form with information that was collected during the Consenting Phone Appointment
  - Enter a note indicating that the interview took place when the participant ID was X (and enter ID in place of X).
  - Set form status as 'Complete'
  - Click 'Save and go to Next Form'
- Go to the Research Assessment evaluation forms under Visit1
  - Forms for Research Assessment evaluation are the following
    - Research Assessment Caregiver – AT
    - Research Assessment Child – AT
    - Research Assessment Caregiver – HA
    - Research Assessment Child - HA
  - Enter a note indicating that evaluation of the visit 1 interview is to be stored under Participant ID X. (and enter ID in place of X)
  - Set form status as 'Unverified' if the evaluation has not been completed. Set form status as 'Complete' if the evaluation has been completed.
  - Click 'Save and go to Next Form'.
- Go to the 'Newest Vital Sign' form under Visit1 if not already there.
  - Enter a note at the end of the form indicating that results of this test are stored under Participant ID X. (and enter ID in place of X)
  - Set form status as 'Complete'

- Click 'Save Record'

In the MICT-DC summary REDCap project

- Click 'Add/Edit Records' and enter the new participant ID for this participant
  - The first three letters of the participant ID must be uppercase and the letter added to the end must be lowercase, i.e. JAX101a.
- Enter data into the 'Participant Information' form
- Set from status as 'Complete'
- Click 'Save Record'

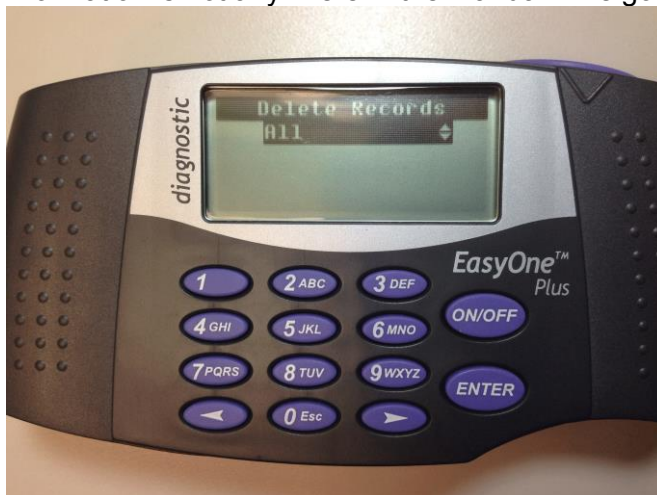
## 5.8. Preparing the EasyOne for a Rescreen Visit 1

### Overview

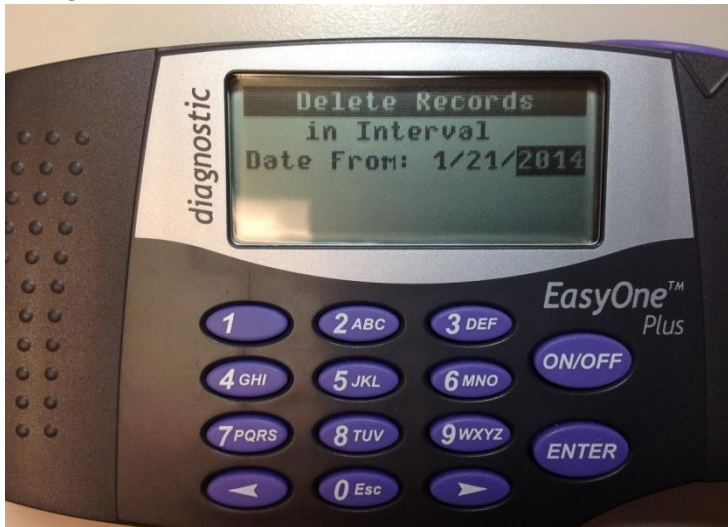
- Delete all the current records for that participant off the EasyOne.
  - Those data will not be used and therefore do not need to be saved anywhere.
  - You need to do this otherwise there won't be enough memory to store PFTs for the next 20 weeks.
- This can be done when they come in to return equipment after screen failure or if you let them keep the device after screen failing, you will need to do this at the Visit 1 rescreen

### SC Procedures

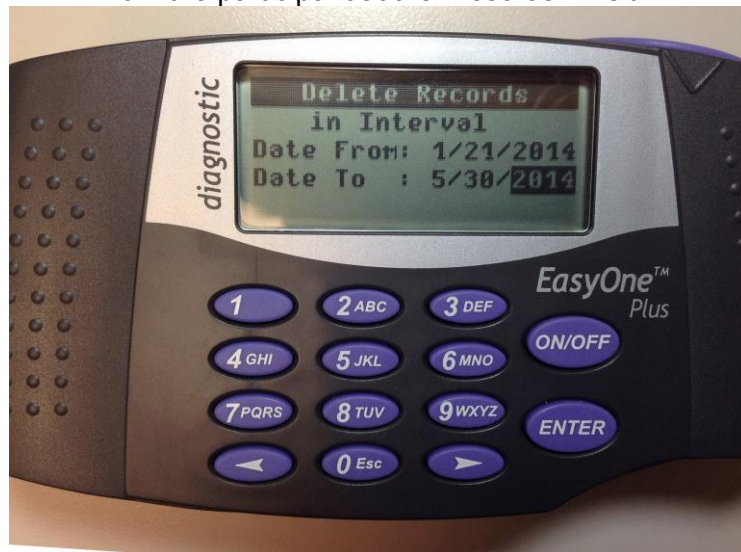
- Connect the EasyOne to the cradle and your computer and download the files.
  - The files will download automatically to the EasyWare program but we won't be using them for any data analysis
- To delete records off the EasyOne, turn on the EasyOne, and then **press 159**. This information is not anywhere in the manual. We got it from the manufacturer.



- You can use the right arrow button to scroll to "in interval". This will allow you to put in the interval of PFT records to delete. You won't be deleting all the demographic information you put in at Visit 1. However, when the participant comes back in at the rescreen Visit 1, you will need to update height and weight.



- Put in the start date for the participant
- Put in the end date. You can put in the current date if you have just retrieved the EasyOne from the participant at their rescreen Visit 1.



- Press ENTER to delete the records.

### 5.9. Recycling a Participant (occurs at Visit 3 only)

#### Definition

Recycling is an additional attempt to randomize a participant into the trial who had successfully passed the stable phase (Visit 1 up to Visit 3) but had failed to meet randomization criteria at V3.

#### Comment

- Recycling will be used only on a case by case basis
- Contact the the PI, Dr. Blake, for permission and specific instructions
- A participant **may be recycled one time**
- Note: A participant ineligible for randomization and for recycling may be re-screened (restarted at V1) The waiting period to rescreen will vary regarding reason for failure to be randomized (use of rescue medication, hospitalization, adherence, etc.)
  - The waiting period will be a minimum of 4 weeks

## 6. Study Staff Training

### Overview

- Provide study-specific training and documentation that staff at the main Clinical Center in Jacksonville and satellite centers have the required approvals, facilities, equipment, personnel, and training necessary to conduct the MICT trial
- Ensure consistent conduct of study procedures over time within and across clinics so that findings from all clinics are comparable

### When

- Before a Clinical Center may schedule participants and conduct study procedures for the MICT study

### Procedures

- Obtain approval of protocol and consents from the IRB and approval of staff at each study site Before a Clinical Center may schedule participants and conduct study procedures for the MICT study
- Review of MICT protocol, manual of procedures, and forms
- Completion of training by all personnel involved in MICT who will be performing the following tasks as Study Coordinator
  - EasyOne spirometry testing
  - Exhaled nitric oxide training using NIOX MINO if being conducted at your site.
    - Operators are not required to be certified but do need to be trained by an Aerocrine representative or someone previously trained by Aerocrine
- REDCap training by Suzanne McCahan, PhD
- iPad training

#### 6.1. REDCap Data System Training with Suzanne McCahan, PhD

Access to the MICT data system will be restricted to those who have taken MICT REDCap training and who have REDCap log in and passwords. Each Clinical Center will be required to have at least one person certified for data entry, although having more than one person certified is advised. The Clinical Coordinator must be certified.

Staff members who are experienced data system operators for previous REDCap studies must also receive training to be granted access to the MICT study in REDCap.

Study staff who are not familiar with the REDCap system can watch a short (15 minute) video that gives a nice overview of data entry in REDCap. The video is called 'Data Entry Overview' and can be found on the following web page. The video can be viewed without logging into REDCap.

<https://apps.nemoursresearch.org/redcap/index.php?action=training>

Study staff who do not have a access to REDCap will complete the online form at the following link to request a REDCap account.

<http://www.nemoursresearch.org/admin/redcapacct.php>

After the REDCap account is set up, the new user will be granted rights to the REDCap project. The user will receive email verification from REDCap team that their username is activated for MICT data entry

The data system will be accessed via the internet from the REDCap web page at

<http://www.nemoursresearch.org/admin/redcapacct.php>

Access to any part of the MICT data system requires a username and password. Once a staff member has completed MICT training his or her username and password will be authorized for data entry. If the staff member was previously certified for data entry they should use their

unique password to enter the REDCap data system. If the staff member was not previously granted access, the temporary password should be used as the default password. The system will instruct the user to create a unique password the first time that user logs in to the data system. From that time forward, only the user's unique password will work.

*\* If a coordinator has been granted access to REDCap they do not need to redo the log in request to MICT. In this case, please notify REDCap staff of this when submitting other certification materials.*

## 7. Study Equipment and Supplies

The JAX site will obtain all of the following supplies and ship them to sites as needed.

### 7.1. Equipment and Supplies Provided by JAX to all Sites

- iPad 2
  - For the participant with Otter Box case: iPad 2 and Otterboxes are sent to the site by the AC at the Jacksonville site after logging the serial numbers for each piece of equipment. (**Click this link to see the iPad distribution logs: [iPad Distribution Log.](#)**)
  - For the Study Coordinator with Otter Box case: These iPads are sent the same way as the participant's equipment.
- EasyOne Spirometer
  - These are shipped to the study site by the Jacksonville AC after property tags and serial numbers are logged into the file located on the JAX S drive. (**Click this link to see the EasyOne spirometer and cradle distribution logs: [EasyOne Spirometer and Cradle Distribution Log.](#)**)
- EasyOne Spirometer cradle - one for each site:
  - This is shipped each coordinator and logged in the EasyOne file on the JAX S drive (**Click this link to see the EasyOne spirometer and cradle distribution logs: [EasyOne Spirometer and Cradle Distribution Log.](#)**)
- EasyOne Mouthpieces: 4 Spirettes are included with each EasyOne Spirometer
  - A spirette can be used for 2 weeks unless the participant is ill, then it should be replaced sooner.
  - JAX can send additional spirettes upon request.
- Blood draw supplies
  - Tourniquet, gauze, alcohol prep pads, bandaids, needles, etc.
  - Collection and storage tubes
    - Blood - for plasma for storage and paced cells for DNA
      - Collection: Vacutainer K2 EDTA 10.8mg-6mL (1 tube)–(BD368661)
      - Storage: 2.0mL cryovials, orange top (2 tubes)
    - Blood - for serum Phadiatop test
      - Collection: SST™ Tube with Silica Clot Activator, Polymer Gel, Silicone-Coated Interior (2 tubes) (BD367986)
      - Storage: 5mL Sarstedt vials, red cap (2 tubes)
  - Cryo pen
  - Labels for blood draw tubes and storage
- NIOX MINO (exhaled nitric oxide) for those sites doing the test
  - Sensors (test kit)- can order 50, 100, 300, or 600 tests per kit. **Note:** The sensors have a 12 month shelf life
  - Scrubber - **Note:** the scrubber is good for 12 months or 1000 tests, whichever comes first)
  - NIOX filters - are included with the Sensor test kits

Sample pricing – Subject to change

**09-1000 NIOX MINO** (Shipping \$30) \$2,995

(Contains: Unit, Adapter, Manual, USB Cable, USB Drive with Visual Incentive Program, NO Scrubber, and QC Plug)

**Test Kits: \$15.96 per test**

**03-4002-US NIOX MINO Test Kit 50** (Shipping \$20) \$798

(Contains: 1 Sensor for 50 tests and 100 NIOX Filters) **\$15.95 per test**

**03-4000-US NIOX MINO Test Kit 100** (Shipping \$25) \$1,595

(Contains: 1 Sensor for 100 tests and 150 NIOX Filters) **\$11.65 per test**

**03-4001-US NIOX MINO Test Kit 300** (Shipping \$40) \$3,495

(Contains: 1 Sensor for 300 tests and 350 NIOX Filters) **\$9.83 per test**

**03-4003-US NIOX MINO Test Kit 600** (Shipping \$80) \$5,895

(Contains: 2 Sensors for 300 tests and 650 NIOX Filters)

**Accessories:**

09-1005 NIOX MINO Power Supply Unit \$95

09-1010 NIOX MINO USB Cable \$40

09-1020 NIOX MINO Bag \$50

09-1025 NIOX MINO USB Visual Incentive Program \$150

09-1026 NIOX MINO Data Management Program \$199

**09-1300 NIOX MINO NO Scrubber \$70**

EPM-000109 NIOX MINO User Manual N/C

## 7.2. Ordered by Each Site

- Dry ice for specimen shipping
- Shipping containers

# 8. Study Procedures

## 8.1. MyNemours Account Set-up (by AC)

### Overview

- Each user has a personal MyNemours account with a unique ID number and password, which means a family could have three different accounts (for mom, dad, and child), with three different passwords
- Nemours requires proof of guardianship in the medical record for access to be granted to the Legal Guardian. This can be the Delaware Care Giver form or appropriate court documentation
- Parents and Legal Guardians can have access to their child's medical record when the child is under 18. When the child is between the ages of 12 and 17 certain aspects of the medical record are no longer viewable. This is because federal and state laws require us to protect certain aspects of an adolescent's medical record
- At age 18 your child is legally an adult and MyNemours access for the parent will automatically terminate
- Patient's can have access to their own MyNemours account at any age
- Parents, Legal Guardians and Patients can grant access to MyNemours for other individuals by filling out the "Authorization to Disclose PHI to a Name Individual via MyNemours". This form is available at Nemours and can be filled out online.  
[https://mynemours.nemours.org/default.asp?mode=stdfile&option=faq#EQ\\_what](https://mynemours.nemours.org/default.asp?mode=stdfile&option=faq#EQ_what)

### When

- MyNemours accounts for a parent and participant need to be set up before the WebEx for the Research Assessment interview is conducted.

### Procedures

- Obtain approval of protocol and consents from the IRB and approval of staff at each study



site Before a Clinical Center may schedule participants and conduct study procedures for the MICT study

- How to Sign Up
  - A parent (or legal guardian) can sign up for MyNemours to gain online access portions of your child's medical record
- What is Needed
  - Internet connection with an updated browser
  - Access code
- How does a Family get an Access Code
  - The AC will work with the family to get MyNemours set up
  - In a usual clinic setting, the parent would let the office staff know they want access to access MyNemours. The parent will sign the necessary Patient User, Proxy User, and/or Assent agreements and will also create a security question. Remember it because they will use it later when you create a MyNemours account
- Setting up MyNemours Account for the Study
  - Check EPIC to see if they have registered for MyNemours
    - In Patient Demographics, look in the Appointment Desk page at the top. The MyNemours status will be Activated, Inactive, or have no information
      - If inactive with no further information, the parent has never set up an account
      - If you see “Activation Code Generated First Time but not Used”, the parent has set up the account but not activated it.
- Suggested Script when Discussing Setting up a MyNemours for the MICT Project (suggested by the MyNemours team at Nemours)
  - I am excited to share with you how MyNemours will make it easier for you to access and review the documents that are required to participate in the MICT study. This program is a free, confidential, internet based tool that gives families interested in participating in our study the ability to review and sign consent for a study with only a few steps without coming into the clinic and meeting with a coordinator.
  - MyNemours does require you to register which I can assist with; you will have a unique User ID and password to access confidential patient information in MyNemours as well as study consents.
  - Some of the other benefits of registering are
    - Communicate with your doctor
    - Access your test results
    - Research related medical information
  - If you have access to a computer and have an internet connection let's get started; first you'll need an activation code to create you're my Nemours account. (above you say that they are required to register “which I can assist you with, will your staff be creating the accounts or will you be directing them to this link) Please connect to the internet and go to [www.Nemours.Org](http://www.Nemours.Org) once on the website look for the MyNemours link in the purple box on the left you can Request an Activation Code online, provide the necessary information, and receive an activation code via email within 3 days.
  - Once you receive the activation code there are three steps you'll have to complete at <https://mynemours.nemours.org/accesscheck.asp> to gain access to your account.

## 8.2. Spirometry

### 8.2.1. EasyOne

#### Overview

- The EasyOne is a hand held light-weight spirometer that participants will use for home



measurement of peak expiratory flow (each morning) and PFT (at each study visit in clinic or by FaceTime). The EasyOne minimizes the need for maintenance due to its unique ultrasound technology. EasyOne does not need calibration and remains consistently accurate over years. The spirette breathing tube assures perfectly hygienic conditions for every patient even if the spirometer is frequently used.

### Training

- Study staff will be trained by the JAX study coordinator on set up and use of the EasyOne.

### 8.2.2. Standard Procedures for Spirometry (Acceptability / Reproducibility)

#### Purpose

- Measure FEV<sub>1</sub> (the amount of air expired in the first second during a forced expiratory maneuver) and FVC (forced vital capacity).

#### When

- All clinic and FaceTime visits

#### Standardization

- Equipment and procedures are based on the ATS recommendations for accuracy and precision
- All personnel certified pulmonary function technologists (National Board of Respiratory Care) **or** receive sufficient instruction from qualified instructors to perform the procedure according to acceptable standards
- All sites will use EasyOne Plus Spirometer.
- There are instructions for the coordinator for EasyOne set up and use.
  - **(Click this link to view the coordinator EasyOne manual: [Manual for Coordinator EasyOne Instructions.](#))**
- There are instructions for the participant for EasyOne use.
  - **(Click this link to view the participant EasyOne manual: [Manual for Participant EasyOne Instructions.](#))**
    - The participant EasyOne manual is pre-loaded on the iPad.

#### Predicted Values

- Calculated according to the published predicted values (Hankinson et al). Calculate online using the LASST pulmonary function calculator. To access the online calculator go to the LASST website: <http://www.jhcct.org/Secure/LASST/LASSTHome.asp> and follow the link to the LASST data system page and then to the LASST calculator

#### Participant Preparation

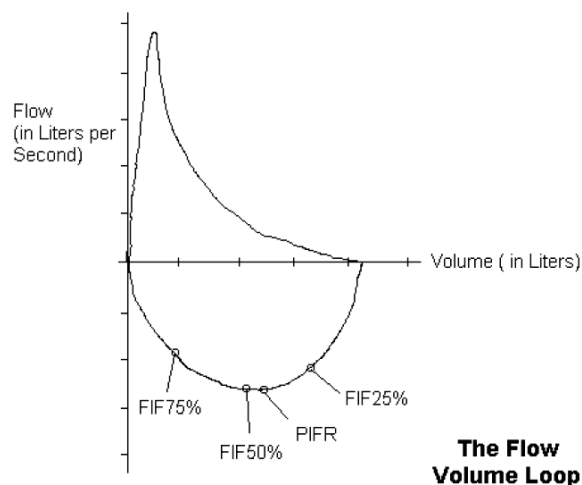
- No use of albuterol or xopenex within 4 hours
- Participant is seated with feet flat on floor
- Participant is wearing nose clips
- Restrictive clothing is loosened

#### Testing Procedure

- Participant Instructions
  - Full inhalation to capacity
  - Seal lips around spirette to avoid leaks around lips and take care not to block the spirette opening with teeth or tongue.
  - Blast out as hard and fast as possible
  - Continue blowing until lungs are completely empty and for at least 6 seconds
- Recognizing a Poor Effort
  - Observe the participant
  - View Quality messages displayed on device after each effort
  - Review proper technique with participant
    - Coordinator should use enthusiastic coaching techniques to use during the maneuver to maximize your chances of getting quality results with a minimum

number of efforts

- **Caution:** Pulmonary function tests require maximum effort on the part of the patient and may lead to dizziness or giddiness
- **Acceptability Criteria**
  - **Test start:** The peak flow should be sharp on Flow Volume curve. Participants may need coaching to get this right (e.g. BLAST it out)
  - **Cough:** This can cause flow irregularities. Reject test when cough is within the first one second (FEV1 will not be accurate). Cough in the later part of the VC is not a reason per se to reject the effort. Often cough can be reduced by asking the participant to exhale SLIGHTLY less forcefully
  - **End of expiration:** When the expiratory effort lasts at least 6 seconds. Participants with severe obstructive lung disease may continue to exhale for 10 or more seconds. Occasionally, premature glottis closure causes abrupt test end. Participants may need to relax and try again with slightly less than maximum effort
  - **Forced inspiration:** Maximum inspiratory effort following the end of expiration as shown on flow-volume curves [NOTE: we are not doing inspiratory maneuvers but if the participant does it reflexively then that is fine.]
- **Reproducibility Criteria**
  - **Definition:** Using the two criteria of FVC and FEV1 to determine how well each acceptable effort compares with the largest acceptable effort
  - The EasyOne selects the best test as the maneuver with the highest SUM of the FVC and FEV1. This is not the procedure for MICT.
    - You will need to calculate the difference between FVC and FEV1 values per the bullets below
  - **FVC:** The second largest FVC should be within .15 L of the largest acceptable FVC
  - **FEV1:** The second largest FEV1 should be within .15 L of the largest acceptable FEV1
  - At least 3 acceptable and 2 reproducible efforts should be obtained. If this cannot be obtained after approximately 8 attempts, then the testing should be halted
    - The EasyOne selects the best test as the maneuver with the highest SUM of the FVC and FEV1. This is not the procedure for MICT.
    - You will need to calculate the difference between FVC and FEV1 values per the bullets above
  - The largest acceptable FEV1 and FVC are recorded on the data collection form. These do not have to be taken from the same maneuver
  - Inspiration may or may not be required but is shown in figure below.



- **Pre- and Post-bronchodilator Testing** follow the instructions in the Coordinator EasyOne manual. **(Click this link to view the coordinator EasyOne manual: [Manual for Coordinator EasyOne Instructions](#).)**
  - Document if it has not been 4 hours since the participant last used albuterol or Xopenex
  - Have participant do 3 pre-bronchodilator efforts.
  - Take picture of the flow volume curves using your iPad by holding down the power button at the same time as holding down the home key
    - These are saved to ensure we have data should the EasyOne get lost or broken
    - Save the photos on the shared drive at
    - Use the following format for file saving: **JAX102\JAX102V5\_07-10-14**
  - Record the PFT Data using the MICT PFT Worksheet. **(Click here to view the [PFT FaceTime Worksheet](#).)**
    - Ensure FEV1 is still  $\geq 70\%$  predicted using the predicted calculator found on the ACRC website at <https://www.jhcct.org/Secure/LASST/LASSTPFT.asp>
    - Calculate the % Predicted value as  

$$\% \text{ Predicted} = 100 * [\text{FEV1 (in Liters)} / \text{Predicted FEV1 (in Liters)}]$$
    - Have participant take 2 puffs of ProAir and wait 15 minutes
      - Can end FaceTime and restart in 15 minutes
    - Have participant do 3 post-bronchodilator efforts using same procedure as for pre-bronchodilator testing
    - Save the handwritten PFT Worksheets until the end of the study.
      - This worksheet will be needed in order to reconcile all the PFT data downloaded from the EasyOne device at Visit 6 with the data entered into REDCap.

### Troubleshooting

- Refer to Troubleshooting Tips in the manufacturer's Easy One Plus user manual. **(Click this link to view the [EasyOne manufacturer's Operator's \(not the technical\) manual: EasyOne Operator's Manual](#).)**

### Quality Messages in EasyOne

- The quality messages assist you in conducting the measurement. After each test, they provide information as to whether the test is acceptable or what to do to improve the result

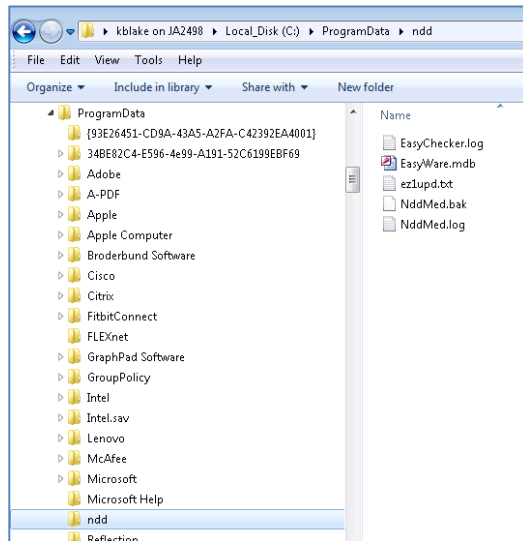
Message	Criterion	Recommended action
Don't hesitate	Back-extrapolated volume greater than 150 ml or 5% of FVC whichever is greater (for age $\leq 6$ : 80ml or 12.5% of FVC whichever	The patient must exhale all air at once and not exhale in short bursts.
Blast out faster	Time until peak flow greater than 120 ms	The patient must exhale more explosively and as firmly and quickly as possible.
Blow out longer	Expiration time less than 2 seconds or volume during last 0.5 seconds $>40$ ml when expiration time is $<6$	The patient stopped exhaling too early. The patient must exhale still further and force as much air as possible out of his or her
Good effort, do next	Test meets above criteria	Good test. Only one to two more good tests and the test is complete.
Blast out harder (only in Frontline mode)	Peak flow not reproducible. Difference with respect to best test greater than 1.0 l/s	The test differs greatly from previous best test. The patient can blow even more firmly and achieve a higher peak flow.

Wait until buzz before blowing out	The time to peak flow (PEFT) is less than 25ms	Instruct the patient to wait until the baseline setting is finished and the device signals that the trial can start
Cough detected. Try	A cough has been detected	Instruct the patient to avoid coughing during the first second.
Deeper breath	FEV1 or FVC* not reproducible. Difference with respect to best test greater than 150 ml or 100ml if FVC is < 1.0L. (for age ≤ 6: 100ml or 10% of FEV1 or FVC*)	The test differs greatly from previous tests. The patient can inhale even more deeply and exhale even more air.
Test complete	QC grade A or B reached. After 5 trials loosened to include QC grade C. See QC grade documentation.	The test is complete. An adequate number of good tests is available.

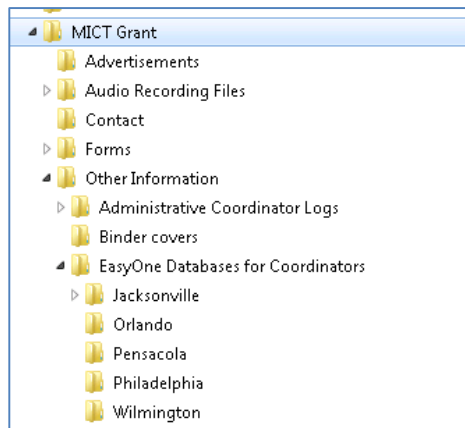
- The The EasyOne will assign grades for flow (FEV1) and volume (FVC) and will provide an assessment of the overall session as follows:

Rating	Criteria in Diagnostic mode	Criteria in Frontline and NLHEP mode
A	At least 3 acceptable tests (for age < 6: 2 acceptable) AND the difference between the best two FEV1 and FVC values is equal to or less than 100ml (80ml if FVC < 1.0 L; for age < 6: 80ml or 8% of FVC whichever is greater)	At least 2 acceptable tests AND the difference between the two FEV1 and FEV6 values is equal to or less than 100ml
B	At least 3 acceptable tests (for age < 6: 2 acceptable) AND the difference between the best two FEV1 and FVC values is equal to or less than 150ml (100ml if FVC < 1.0 L; for age < 6: 100ml or 10% of FVC whichever is greater)	At least 2 acceptable tests AND the difference between the two FEV1 and FEV6 values is equal to or less than 150 ml
C	At least 2 acceptable tests AND the difference between the best two FEV1 and FVC values is equal to or less than 200ml (150ml if FVC < 1.0 L; for age < 6: 150ml or 15% of FVC whichever is greater)	At least 2 acceptable tests AND the difference between the two FEV1 and FEV6 values is equal to or less than 200 ml
D	At least 2 acceptable trials but the results are not reproducible. Quality message "Result not reproducible" OR only one acceptable trial. Quality message: "Only one acceptable trial"	At least 2 acceptable trials but the results are not reproducible. Quality message "Result not reproducible" OR only one acceptable test. Quality message "Only one acceptable trial"
F	No acceptable test available	No acceptable test available



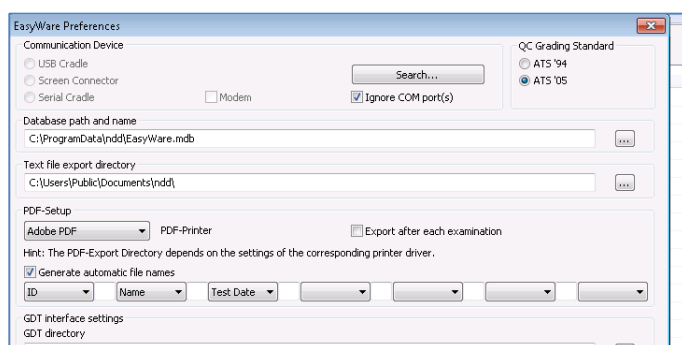


- The name of the database is “EasyWare.mdb”
- Right click on the name of the file and select “copy”
- Navigate to the Jax S drive server
- Navigate to the folder for your site (Jacksonville, Orlando, Pensacola, Philadelphia, St. Louis, Wilmington) in MICT Grant\Other Information\EasyOne Databases for Coordinators. ***(Click this link to go to the folder location: [EasyOne Databases by Site.](#))***

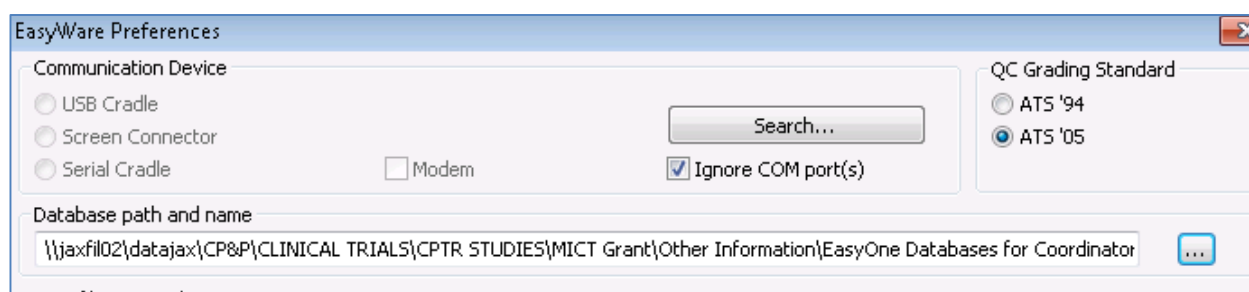


- Right click and Paste the file into the folder for your site
- Rename the file to “EasyWare\_JAX.mdb” with JAX being your site abbreviation (JAX, ORL, PNS, PHL, STL, WIL).
- Step 2: Changing the path that the EasyWare database uses to the Jax S drive
  - Open the EasyWare program on your computer
  - Go to File, then select “Preferences”



[illegible]

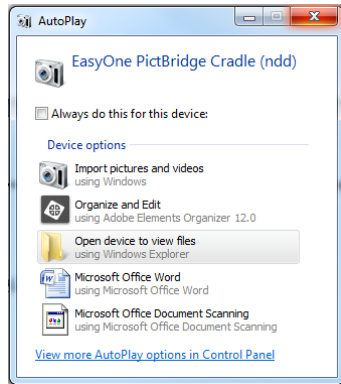
- Click on the three dots to the right of “C:\ProgramData\ndd\EasyWare.mdb”.
- Navigate to the Jax S drive server
- Navigate to the folder for your site in in MICT Grant\Other Information\EasyOne Databases for Coordinators. (***Click this link to go to the folder location: EasyOne Databases by Site.***)
- Click on the database that you just moved there “EasyWare\_JAX.mdb”
- Select “Open” at the bottom of the window
- The “Database path and name” is now set to store all your participants records on the S drive (see below).



### 8.2.5. Syncing the EasyOne using the EasyWare program

## Visit 1

- After the participant has completed the pre- and post-spirometry, connect the EasyOne cradle to the computer with the EasyWare program. Put the participant's EasyOne to the into the EasyOne cradle. The windows AutoPlay will open but just close it.



- Open the EasyWare program
- All the files for that participant will be automatically downloaded
- Select the pre- and post-spirometry tests to print to send to the primary care doctor if the family has provided consent to do so. Unfortunately because of the way the EasyWare is set up, each test is individual rather than having a pre- and post- all in one result.
- Keep a printed copy for your records

### Visit 6

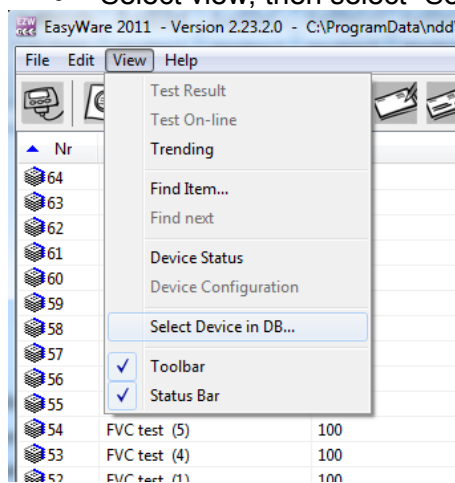
- Repeat the process at Visit 6
- All the PFTs from Visit 2 through Visit 6 will be automatically downloaded.
- Select the pre- and post-spirometry tests to print to send to the primary care doctor if the family has provided consent to do so. Unfortunately because of the way the EasyWare is set up, each test is individual rather than having a pre- and post- all in one result.

## 8.2.6. Viewing Data and Back-up Procedures

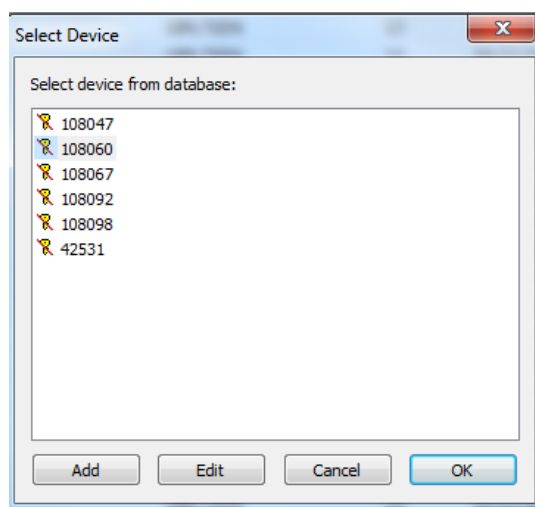
### Viewing All the PFTs from your Participants

The EasyWare database stores ALL the PFTs from all your study participants.

- Open the EasyWare program (without the cradle or any device being attached).
- Select view, then select "Select Device in DB"



- You will now see all the devices for all your participants listed as shown below:



You can select the device number for the participant you wish to view. A spreadsheet lists all the devices that have been sent to each site (***Click this link to go to the folder location: [EasyOne Devices by Study Site.](#)***) Use the excel filters to see data just for your site.

### 8.3. Exhaled Nitric Oxide (NIOX MINO) [only for sites doing this procedure]

#### Purpose

- Measure the fractional concentration of NO in exhaled breath (eNO) using the NIOX MINO®

#### When

- All Visit 1 and Visit 6 before spirometry

#### Overview

- Exhaled NO will be measured with a portable eNO device, the NIOX MINO®. The NIOX MINO® measures eNO at an exhalation pressure range of 10 to 20cm H<sub>2</sub>O and an exhalation flow rate of 50±5 mL/s

#### 8.3.1. Equipment and supplies for Testing

NIOX MINO® unit	The Initial NIOX MINO test supply kit (50 NIOX patient filters, one		
	NIOX® patient	NIOX MINO®	NIOX MINO® test card

			cards are provided for each ACRC Clinical Center.
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### 8.3.2. Quality Control

#### Equipment for Quality Control

- NIOX MINO® QC card (white)
- NIOX MINO® QC filter for Weekly QC testing



#### Quality Control requirements for the NIOX MINO®

- Calibration by the user is not required
- The NIOX MINO® has standardized internal procedural controls that cannot be influenced by the user. Whenever a potential deviation is detected, the appropriate message is presented on the display making it impossible to continue the measurement or alternately, the procedure is aborted. A measurement result is only presented to the operator when the device handling and measurement processes are correctly executed
- The QC test for the NIOX MINO® is a biologic control (Normal Control Tester)
- A “daily” QC test is required on the days when eNO testing is done
- An extended/Weekly QC test should be performed at initial set-up, every 7 days, and when a new sensor is placed in the NIOX MINO®

#### Selection of Normal Control Testers for QC

- Identify staff members who will serve as the Biologic Control (Normal Control Tester) and who fulfill the following criteria
  - Over 18 years of age
  - No ongoing respiratory or sinus infection or known airway disease
  - Nonsmoker
  - Expected stable eNO values between 5 and 40 ppb
  - Preferably no chronic sinonasal disease or asthma

### Initial “Qualification” of Normal Control Tester

- Each Normal Control Tester should have a White QC card with their name written on it.
- With the White QC card inserted into the NIOX MINO, the selected staff member will perform a total of three eNO measurements.
- Only one eNO measurement should be performed per day and all three measurements should be completed within seven days.
- A mean value is calculated from the three measurements. If the mean value is between 5-40ppb it is considered acceptable and the Normal Control Tester is “Qualified”.
- Subsequent QC test results from this Normal Control Tester must be within  $\pm 10$ ppb of the mean value to be a PASS.
- Each normal control tester must perform a QC procedure (daily or extended/weekly) at least once every 28 days to maintain his/her qualification status.

### Performing the QC tests

- Before any QC measurement, the Normal Control Tester should:
  - Avoid nitrate rich food for 3 hrs
  - Avoid any strenuous exercise at least 1 hour
- A Normal Control Tester should not perform a measurement in case of:
  - Ongoing respiratory infection
  - Acute seasonal allergies

### The “Daily” QC procedure

- “Daily” is a misnomer; a Daily QC is required only on days the NIOX MINO® is to be used for participant testing. (A twinkling star next to the breathing cloud on the NIOX MINO® screen indicates the Daily QC needs to be conducted.)
- The Daily QC consists of a standard eNO test performed by a qualified Normal Control Tester with his/her White personal QC card inserted into the NIOX MINO®.
- The steps for the Daily QC test are as follows:
  - Remove the Blue Test card from the NIOX MINO® device and insert the White personal QC card of the qualified Normal Control Tester doing the QC test.
  - The Normal Control Tester should conduct a standard exhalation test (see below for Test Procedures) and wait (1:40 min.) for the screen to display the result.
  - The screen displays the mean value (X) and the difference ( $\Delta$ ) between the mean value and the day’s QC test value.
  - If the difference ( $\Delta$ ) is within  $\pm 10$  ppb of the Tester’s mean value, then the test result is approved and the Daily QC procedure is complete.
  - Remove the White personal QC card and reinsert the Blue NIOX MINO® test card
  - Press the return arrow for return to the menu screen.
  - If the difference between the Tester’s mean value and the day’s QC test value is more than  $\pm 10$  ppb, restart the QC procedure with another qualified tester
  - If the second testers result is not approved, do not proceed with eNO testing. Contact Aerocrine at [service.US@aerocrine.com](mailto:service.US@aerocrine.com) or call (866)275-6469.

### The Weekly/Extended QC test

- The Weekly QC test, also known as the Extended QC procedure, needs to be done as part of the initial set-up, every 7 days, and when a new sensor is placed in the MINO. (An alternating QC icon and breathing cloud on the MINO screen indicates a Weekly/Extended QC procedure needs to be conducted.)
- The Weekly/Extended procedure consists of:
  - A normal control measurement completed by a qualified normal tester (as done

- for the daily QC)
- A measurement of a nitric oxide free sample using the NIOX MINO® QC filter. (The NIOX MINO® QC filter produces a nitric oxide free sample. When the instrument completes its analysis of this sample, it should display a result below the detection limit (< 5 ppb) of the instrument.)
  - After completing the procedure for the “daily” QC test as above, without removing the White personal QC card, attach the QC filter to the NIOX MINO patient filter opening, then attach the NIOX filter to the QC filter.
  - Touch the display screen to activate the instrument.
  - Perform an exhalation test (see below for Test Procedures) and wait (1:40 min.) for the result.
  - If the reading is < 5 ppb, the extended/weekly QC test is complete.
  - Remove the QC filter and the White Personal care from the NIOX MINO.
  - Insert the Blue NIOX MINO card.
  - If the reading is not < 5 ppb, the QC has failed and you need to contact Aerocrine at service.US@aerocrine.com or call (866)275-6469.

**Note: tests performed with the NIOX MINO® unit during the QC procedures will not affect the number of remaining tests on the NIOX MINO® sensor.**

### 8.3.3. Procedure for Measuring Exhaled Nitric Oxide

#### Participant Preparation

- Study participants should be instructed to avoid any food or drink for one hour prior to eNO
- testing.
- Study participants also should avoid any strenuous exercise or smoking for one hour prior to eNO
- testing.
- If possible, participants should avoid bronchodilator use for 2 hours before eNO testing
- eNO measurement should be done before spirometry
- If the participant has an acute upper and/or lower respiratory infection, note this on the NO form.
- If participant used inhaled or oral corticosteroids on the day of the test, record time of most recent use on NO form.
- Do NOT use nose plugs.

#### Test Procedures

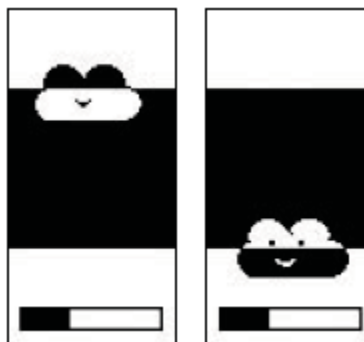
- KEEP DEVICE POWERED AT ALL TIMES (including overnight).
- Make sure the NIOX MINO® sensor is in place.
- Insert a NIOX MINO® patient filter into the unit.
- Make sure the participant is seated during the entire procedure.
- Touch the display screen. When the top light on the unit is lit, the unit is ready for measurement of eNO.
- The participant empties the lungs first, and then inhales deeply through the filter to total lung capacity. The cloud on the display is inflated and the top light is turned off during inhalation. Next, the participant exhales slowly through the NIOX® filter. Visual guidance is provided by the top light and there is also a continuous sound to guide the participant. The participant can also view the display using a mirror.
- You can instruct the participant as follows;
  - First empty your lungs by breathing out as much as possible
  - Next inhale deeply through the filter to total lung capacity



- Then exhale with steady pressure through the NIOX MINO® filter
- As the participant exhales, listen to the sound signals and watch the top light – a continuous sound and a steady light means the test is OK.



Correct exhalation display



Exhalation too hard (left) or too low (right)

- When the exhalation is approved, the sound ceases with a click, and the top light turns off.
- Wait (1:40min.) for the result to be displayed on the screen.
- Record the result on the Nitric Oxide (NO) form.
- If result of eNO <5 ppb, record "0" ppb.
- Repeat the test and record results from second test on NO form
- If results are not consistent between tests, note this on NO form and comment on possible problems.

## 8.4. Specimens

### 8.4.1. Overview of Specimen Collection

#### Visit 1 – Part 2

- Pregnancy test for women of childbearing potential

#### Visit 6 – Part 2

- Blood for DNA and Phadiatop testing and future studies

### 8.4.2. Supplies

#### Provided by the JAX site to all sites

- Blood - for plasma for storage and packed cells for DNA
  - Vacutainer K2 EDTA 10.8mg-6mL (2 tubes)–[BD368661: Vacutainer, 13 x 100mm, 6.0mL, Plus Plastic EDTA Tube, Lavender Conventional Stopper & Paper Label]
    - 2 tubes
  - 2.0mL cryovials, orange top (2 tubes)
    - 2 tubes
- Blood - for serum Phadiatop test
  - SST™ Tube with Silica Clot Activator, Polymer Gel, Silicone-Coated Interior - 5mL (2 tubes) [BD367986: Vacutainer Plus SST Plastic Venous Blood Collection Serum Tube with Gold Hemogard Closure]
    - 2 tubes
  - 5mL Sarstedt vials, red cap (2 tubes)
    - 2 tubes

- Pre-printed, barcoded labels (one label sheet per participant), which are:
  - Participant specific
  - Specimen specific for cryovials (plasma), vacutainer (packed cells) and Sarstedt tubes (serum for Phadiatop) and indicate aliquot #

#### **Provided by the study site**

- Styrofoam box with outer cardboard box (shipper)
- Plastic biohazard specimen bag
- Absorbent sheet
- FedEx air bill
- Cold pack to maintain cool temperature
- Dry ice

### **8.4.3. Blood Collection, Processing, Labeling, and Shipping for DNA, Plasma, Serum**

#### **8.4.3.1. Blood Collection**

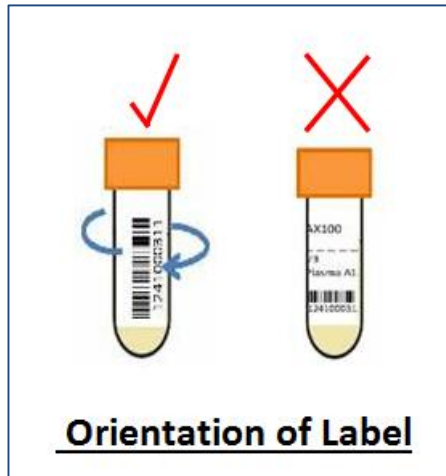
- Supplies needed
  - Tourniquet, gauze, alcohol prep pads, bandaids, needles, etc.
  - Collection and storage tubes
    - Blood - for plasma for storage and packed cells for DNA
      - Collection: Vacutainer K2 EDTA (purple) 10.8mg-6mL (2 tubes)– (BD368661)
      - Storage: 2.0mL cryovials, orange top (2 tubes)
    - Blood - for serum Phadiatop test
      - Collection: SST™ Tube with Silica Clot Activator, Polymer Gel, Silicone-Coated Interior (2 tubes) (BD367986)
      - Storage: 5mL Sarstedt vials, red cap (2 tubes)
  - Cryo pen
  - Labels
  - Cup of ice
- Order of processing
  - Blood for phadiatop (serum) can be sitting to clot while the blood for the DNA/plasma is being processed
  - Try and process specimens within 2 hours of collection
  - After collecting EDTA, mix well by gently inverting 5 to 10 times
    - Keep the EDTA (purple) tubes for DNA and plasma on ice for about 10 minutes before processing
      - This will keep the leukocytes from becoming anerobic
- For sites without a refrigerated centrifuge (instructions on how to take a regular centrifuge and make it cold)
  - Remove and place the swinging rotor/buckets in wet ice (ice+water slurry).
    - Should reach 4°C in 15 minutes.
    - Do not submerge (you want to keep the inside of rotor/bucket dry)
      - If you get water in the rotor/bucket, the water must be completely removed prior to the run, otherwise, the tube might break or the centrifuge will be out of balance

#### **8.4.3.2. Labels for Collection Tubes and Shipment/Storage Tubes**

- See label sheet below for which labels to use for collection tubes and shipment/storage

tubes

- Labeling the tubes:
  - Tubes must be clean, dry and at room temperature!
  - Enter the date on the label
  - Affix the label to the tube taking care to orient the barcode **LENGTHWISE**
    - If the barcode is oriented around the circumference of the tube instead of lengthwise, then the barcode reader will not be able to read the code. If this accidentally happens, then apply a duplicate label over the old label taking care to orient the barcode lengthwise. See the diagram below for correct orientation of barcodes.



- Label sheets:
  - Ed Mougey (904-697-3781, [emougey@nemours.org](mailto:emougey@nemours.org)) will print the labels to be sent to the sites. Contact Ed Mougey if labels are needed.

#### 8.4.3.3. Blood Processing and Shipping Instructions

- See table below for processing and shipping instructions
- IMPORTANT NOTE ABOUT TUBES WHEN FREEZING (see table below)
  - Important to make sure the tubes (especially the purple top) freeze while laying horizontally
    - Otherwise, there is a HIGH probability that the tubes will crack!!!
    - This is also likely true for serum tubes, unless actual cryovials (rather than polystyrene tubes) are used

Specimen	Collection Tube	Label	Processing	Action
DNA and plasma  (DNA is saved for genotyping and plasma is saved for future use)	Vacutainer K2 EDTA 10.8mg-6mL – (BD368661)  2 6mL tubes	Designated labels on Vacutainer Label Sheet and Cryovial Label Sheet	<ul style="list-style-type: none"> <li>Centrifuge the 6mL vacutainer K2 EDTA tube for 7 min at 2000g, <b>4°C</b></li> <li>Immediately remove plasma from Vacutainer tube and aliquot into 2mL orange cryovials. Label cryovials.</li> <li>Firmly replace HemoGuard closure on the Vacutainer</li> <li>Freeze Vacutainer (containing the packed cells) and cryovials at <b>(minus) 80°C</b>. If no (minus) -80°C freezer available, then freeze in (minus) -20°C <u>non frost-free</u> freezer for up to 1 week before shipping.</li> <li><b>Note:</b> To prevent packed cells tube breakage, lay tube horizontally in the (minus) -80°C [or (minus) -20°C] freezer for 20 minutes, or until frozen, prior to storing then in freezer boxes</li> </ul>	<p>Batch ship both plasma and packed cells together on dry ice (frozen) priority overnight to:</p> <p>Pharmacogenetics Center c/o Ed Mougey Research, 9th floor Nemours Children's Clinic 807 Children's Way Jacksonville, FL 32207</p> <p>Upon shipment, send email to: <a href="mailto:emougey@nemours.org">emougey@nemours.org</a></p>

<p>Phadiatop (serum). While phadiatop is clotting, the DNA/plasma tube can be processed.</p>	<p>SST™ Tube with Silica Clot Activator, Polymer Gel, Silicone-Coated Interior (BD367986)</p>	<p>Cryovial Label sheet</p>	<ul style="list-style-type: none"> <li>• Allow sample to clot for about 30 minutes at room temperature.</li> <li>• Centrifuge at 1000g for 10 minutes at room temperature (it is OK to use the centrifuge if it is still cold after processing DNA/plasma.)</li> <li>• Place a minimum of 0.5mL of serum into each of the 5mL red top tube(s) (Sarstedt Inc.)</li> <li>• Sample is to be divided between 2 tubes (unless there is less than 1mL of serum). If &lt;1mL of serum, then just put it all in 1 tube to send to DACI. If there is enough for 2 tubes, send the 2<sup>nd</sup> tube to JAX (Ed Mougey, PhD)</li> <li>• Store in <b>(minus) -80°C</b> freezer. If no (minus) -80°C freezer available, then freeze in (minus) -20°C <u>non frost-free</u> freezer for up to 1 week before shipping.</li> <li>• Can be shipped on cold packs or with dry ice</li> <li>• <b>Note:</b> To prevent tube breakage, lay serum tubes horizontally in the freezer for 20 minutes, or until frozen, prior to</li> </ul>	<p>Samples for Phadiatop will be shipped to Nemours and Nemours will ship them to the DACI lab at the end of the trial. Samples are to be kept in storage at the site until shipment to Nemours. The results can be included in the participant's medical record.</p> <p><b>DACI lab:</b> Robert G. Hamilton, Ph.D., JHU DACI Reference Laboratory Johns Hopkins Asthma and Allergy Center Room 1A20 5501 Hopkins Bayview Circle Baltimore, MD 21224, USA Tel: 410-550-2029</p>
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Specimen	Collection Tube	Label	Processing	Action
			storing then in freezer boxes.	

#### 8.4.3.1. General Shipping Instructions

- Batch ship frozen samples (serum, plasma and packed cells) every three months if stored at -80°C; otherwise if stored at -20°C then need to ship within 1 week.
  - Ship on Monday, Tuesday, or Wednesday only, and not within 3 days of a holiday
- Make sure clinic staff members preparing shipments
  - are up-to-date with current IATA and DOT regulations regarding human blood shipments
  - have completed compliance training
    - the course is available on Nemours University (Shipping Hazardous Materials-Infectious and Biological Substances)
    - After course completion, send document to Michael Primiani, Regulatory Affairs Manager ([Michael.primiani@nemours.org](mailto:Michael.primiani@nemours.org)) and he will send you a certificate.
- Affix proper labels on outside of cardboard box
  - UN3373 label
  - Dry ice label (UN1845)
- Bubble wrap should be wrapped around specimen bags to provide additional protection
  - Ship Priority Overnight
  - For item #6, Special Handling, indicate "Yes, Shipper's Declaration not required"
  - For item #6, Special Handling, check "Dry Ice" and fill in weight of dry ice in kilograms (10 lbs = 4.4 kg)
  - Immediately upon shipment, notify lab by sending email to: [emougey@nemours.org](mailto:emougey@nemours.org)
    - Include tracking number for shipment in email
- Include Specimen Transmittal Form
  - Complete Specimen Transmittal Form(***Click here to view the [Lab Specimen Transmittal Form](#) to ship to Nemours***)
  - Upon receipt of the samples, Ed Mougey, PhD (Jacksonville) and the person at DACI will complete the confirmation of specimen receipt on the Speciman Transmittal Sheet
    - Dr. Mougey will email a copy of the transmittal form to the study coordinator
    - The study coordinator will upload the transmittal form into the participant's record in REDCap
  - Example of completed transmittal form



# Nemours

Center for Pharmacogenomics and Translational Research  
807 Children's Way  
Jacksonville, FL 32207

(904)-390-3600

# MICT

Specimen Transmittal Form (ST) version 1.0

Site: JAX ☒, ORL ☐, PNS ☐, FTM ☐, WLM ☐

Coordinator: Nancy Archer

Date: Jan. 23, 2015

Please Ship Specimens to:

Edward B. Mougey, Ph.D.  
Nemours Children's Clinic  
807 Children's Way  
Jacksonville, FL 32207  
Phone: (904) 697-3781  
Email: emougey@nemours.org

Note: Please do not ship after Wednesday or within two days of a Holiday!

Patient ID	Sample Type	Number of Aliquots Shipped	Number of Aliquots Received	Comments
JAX102a/ESPIE	Cells (DNA) <input checked="" type="checkbox"/>	1	1	obtained + taken to lab on 8/14/14 (w) error 1/23/15 (samples to Astide A.)
	Plasma <input checked="" type="checkbox"/>	1	1	
	Serum <input type="checkbox"/>			
	Phadiatop <input checked="" type="checkbox"/>	2	2	
JAX113a/SXMAR	Cells (DNA) <input checked="" type="checkbox"/>	1	1	obtained + taken to lab 8/14/14 (samples w) given to B. Dughi
	Plasma <input checked="" type="checkbox"/>	1	1	
	Serum <input type="checkbox"/>			
	Phadiatop <input checked="" type="checkbox"/>	2	2	
JAX128/KRWIL	Cells (DNA) <input checked="" type="checkbox"/>	2	2	taken to lab on 1/22/15 (w) specimens given to S. Swartz
	Plasma <input checked="" type="checkbox"/>	2	2	
	Serum <input type="checkbox"/>			
	Phadiatop <input checked="" type="checkbox"/>	2	2	
	Cells (DNA) <input type="checkbox"/>			
	Plasma <input type="checkbox"/>			
	Serum <input type="checkbox"/>			
	Phadiatop <input type="checkbox"/>			

Coordinator Signature: Nancy Archer

Date: 1/23/15

Received By: E. Mougey

Date: 1/23/2015

Condition Received: In Spec

Page: 1 of 1

#### 8.4.4. General Requirements for Specimen Collections

##### GCP

- Gloves must be worn at all times when handling specimens. This includes during removal of the rubber stopper from the blood tubes, centrifugation, pipetting, disposal of contaminated tubes, and clean-up of any spills.
- Tubes, needles, and pipets must be properly disposed of in biohazard containers, in accordance with institutional requirements.
- Universal precautions and OSHA (Occupational Safety and Health Administration) and institutional requirements (<http://www.osha.gov/SLTC/biologicalagents/index.html>) should be followed, including gloves, eye protection or working in a biosafety cabinet for blood processing.
- To maintain samples at 4°C, sample can be placed on ice, in ice bath or in refrigerator (if at 4°C/39°F)

### 8.5. Participant Education and Instructions

#### 8.5.1. Overview

##### To Provide Information to Coordinator for Instructing Participants

- Temporary Asthma Action Plan (TAP)
- MICT Asthma Action Plan (AAP)
- Instructions for MICT Morning and Evening Reports
- MICT Schedule of Visits

#### 8.5.2. Asthma Action Plans (AAP)

##### Purpose

- To inform participants of appropriate management of asthma symptoms

##### When

- At all in clinic and FaceTime visits

##### Tasks and Functions

- **Temporary Asthma Action Plan (Visit 1 – Part 2 (Clinic))**
  - When the REDCap procedures are followed, the AAP will prepopulate with the participants
    - Name (name is NOT shown on the iPad for the participant due to HIPAA requirements)
    - Date
    - Personal best PEF based on PFTs done at the visit
    - Red, Yellow, and Green zone PEF limits
    - Primary asthma care doctor name and phone number
    - Study coordinator name and phone number
  - Print a color copy for the participant at Visit 1 – Part 2 (Clinic)
    - Go to MICT-data REDCap project
      - Under “Project Bookmarks” select “Print Asthma Action Plan”
      - Enter the Participant ID
      - Print AAP
  - The AAP in full color is available on their iPad
  - This AAP will appear from Visit 1 until Visit 3
  - HINT: The completed Temporary Asthma Action Plan **will only display** if the following

information is entered:

- The Pulmonary Function Testing form: The highest of 3 PEF efforts has been entered (the Temp Asthma Action Plan form will prepopulate with the red, yellow and green zone values)
  - Study Information form: Study Coordinator name and phone number
  - Participant Information form: Participant name, Physician name and phone number
  - Visit Date form: Target dates for Visit 1 and Visit 3; actual date for Visit 1
- **Study Asthma Action Plan (Visit 3)**
    - When the REDCap procedures are followed, the AAP will prepopulate with same information as above except
      - The PEF values will be based upon a mean of the 10 of the last 14 days of Morning Report PEF data
    - Print a color copy and mail to the participant with the randomized study drug
      - The coordinator may have to print it and provide to the pharmacist; the AC will print it for sites that JAX is managing drug shipment
    - This AAP will appear from Visit 3 to Visit 6
    - HINT: The completed Temporary Asthma Action Plan **will only display** if the following information is entered:
      - The Pulmonary Function Testing form: The highest of 3 PEF efforts has been entered (the Temp Asthma Action Plan form will prepopulate with the red, yellow and green zone values)
      - Study Information form: Study Coordinator name and phone number
      - Participant Information form: Participant name, Physician name and phone number
      - Visit Date form: Target dates for Visit 1 and Visit 3; actual date for Visit 1 and Visit 3
  - The AAP is programmed to appear on the iPad anytime a PEF below 85% is entered on the Morning Report (indicating they are in the yellow zone)
  - The AAP is always available to the SC on the REDCap site at <https://apps.nemoursresearch.org/mict/admin/actionPlan.php>
    - Enter your Nemours user name
    - Enter password "MICTstudy2013"; select Enter
    - Enter the Participant ID
- OR
- Go to MICT-data REDCap project
    - Under "Project Bookmarks" select "Print Asthma Action Plan"
    - Enter the Participant ID
    - Print AAP

## 8.6. Treatment Failure

### Purpose

- To identify a treatment failure

### Definition

- Treatment failure is defined as the occurrence of the following after participant has been randomized to study treatment (from V3 to V6). For purposes of this study, a "treatment

failure” will include any and all of the following events that occur between visits

- Asthma exacerbation
  - Hospitalization or urgent medical care visit for asthma initiated by the participant or physician (REDCap sends alert email to coordinator when entered on Evening Report)
  - Use of systemic corticosteroids for asthma or increase in controller therapy as determined by Study Physician or asthma care provider (REDCap sends alert email to coordinator when entered on Evening Report)
  - Decrease in pre-bronchodilator FEV1 to more than 20% below baseline (pre-BD FEV1 at Randomization) at any time during study (you will need to calculate this – Use the PFT Worksheet. ([Click here to view the PFT FaceTime Worksheet.](#)))
  - Decrease in morning PEF to more than 35% below baseline mean PEF on two consecutive days (REDCap sends alert email to coordinator if value entered on Morning Report meets this criteria)
    - Baseline mean PEF is the mean PEF during the final 2 weeks of open-label Advair (stable phase)
  - Use of 10 or more puffs per day of rescue beta-agonist for 2 consecutive days (excluding uses as a pre-medication for exercise). One nebulizer use is equivalent to 2 puffs of beta- agonist. (REDCap sends alert email to coordinator when entered on Evening Report)
- Participant refusal to continue due to medication intolerance or failure of the treatment to provide symptomatic relief (REDCap sends alert email to coordinator when entered on Evening Report)
- Judgment by physician that participant should be withdrawn from study treatment for reasons of safety

### When to Assess

- The coordinator should assess for treatment failure anytime one of the above alerts is received
- The coordinator should assess at each FaceTime visit using the REDCap form “Assessment for Treatment Failure”

### Procedures

- The participant can continue with study procedures through Visit 6 if the participant has been randomized at Visit 3
  - Following first treatment failure, participant is to be treated according to best medical judgment and may continue in the same treatment group.
    - Participants who experience an exacerbation of their asthma or have other significant signs of worsening of their asthma will be referred to their primary care physician or asthma provider for re-evaluation of their asthma regimen.
    - If their personal provider is unavailable in a timely manner the clinical center physician will evaluate the participant’s treatment regimen and make recommendations for treatment.
  - If an individual participant has two treatment failures (e.g. asthma exacerbations) requiring the use of systemic corticosteroids, the participant will be taken off study treatment and continue in the study on alternate treatment according to best medical judgment. Alternate treatment will be according to the discretion of his/her treating physician or by Study Physician if personal asthma care provider is

- unavailable.
- The goal is to continue with all follow-up visits, for all participants that are randomized
- If a participant is being withdrawn from the study, complete Visit 6 procedures

### Guidelines for Suggested Treatment Failure Response

- Final decision to be made by treating physician or study physician. All treatment decisions should be made according to best medical judgement

Treatment Failure Occurrence		Response
Change in asthma*	Acute Exacerbation**	
None	1	Change in treatment if in best medical judgement
1 <sup>+</sup>	None	Continue treatment with study drug
1	1	Change in treatment if in best medical judgement
2	None	
None	2	Two treatment failures that require use of systemic corticosteroids results in participant being taken off study treatment. Proceed with new treatment according to best medical judgement

\*change in asthma

- Decrease of Pre-BD FEV<sub>1</sub> to more than 20% below baseline AND/OR
- Decrease in morning PEF to more than 35% below baseline (at V3) AND/OR
- Use of 10 puffs or more of rescue medication (e.g. albuterol for 2 consecutive days)

\*\*Acute Exacerbation

- •Use of oral/systemic corticosteroids or increase in controller therapy AND/OR
- •Hospitalization for asthma AND/OR
- •Hospitalization (severe—ICU/intubation) for asthma

## 9. Event Recording (AE, SAE, Administrative Events)

### 9.1. Adverse Events

#### Purpose

- To report an adverse event

#### Definition

- Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related
- Unexpected or Unanticipated Problem
  - “unexpected” if it is not listed in the investigator brochure or is not listed at the specificity or severity that has been observed; or an investigator brochure is not required or available, is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended.
- Relatedness (determined by the study physician)
  - Relatedness refers to the extent to which an adverse event is considered to be

related to the intervention or study procedures. An adverse event is considered related if there is a reasonable possibility that the event may have been caused by the procedure. The following definitions apply:

- Unrelated
  - Adverse event is clearly due to extraneous causes (e.g., underlying disease, environment)
- Unlikely (Adverse event must have 2 of the following):
  - Does not have temporal relationship to intervention,
  - Could readily have been produced by the subject's clinical state,
  - Could have been due to environmental or other interventions,
  - Does not follow known pattern of response to intervention,
  - Does not reappear or worsen with reintroduction of intervention
- Possible (Adverse event must have 2 of the following):
  - Has a reasonable temporal relationship to intervention,
  - Could not readily have been produced by the subject's clinical state,
  - Could not readily have been due to environmental or other interventions,
  - Follows a known pattern of response to intervention
- Probable (Adverse event must have 3 of the following):
  - Has a reasonable temporal relationship to intervention,
  - Could not readily have been produced by the subject's clinical state or have been due to environmental or other interventions,
  - Follows a known pattern of response to intervention
  - Disappears or decreases with reduction in dose or cessation of intervention
- Definite (Adverse event must have 4 of the following):
  - Has a reasonable temporal relationship to intervention,
  - Could not readily have been produced by the subject's clinical state or have been due to environmental or other interventions,
  - Follows a known pattern of response to intervention,
  - Disappears or decreases with reduction in dose or cessation of intervention and recurs with re-exposure

### **When to Assess**

- Adverse events are assessed on a continual basis through the study from data collected on the Morning/Evening Reports, FaceTime appointments, onsite appointments, etc.

### **Study Physician Role**

- Reviews AE
- Determines severity
- Determines relatedness to study drug

### **Procedures**

- The Adverse Events Worksheet is under the column "Ongoing"
  - All adverse events will be recorded on this form throughout the participant's trial participation
- Follow the instructions on the form
- If the "Outcome of event" is "ongoing" at the time the form is completed, it can be updated to one of the other choices at a later date when an outcome is known.
  - When making changes to the "Outcome of event" from "ongoing" to another outcome choice, you must include a short explanation in the call out bubble.



- This information will then be stored in the event history along with the person making the change
- The physician will be required to complete:
  - Whether the event serious
  - Whether the event was related to the study drug or a study procedure
- If there are multiple events, a second adverse event form will become available as soon as data is entered into “Adverse event name”

### Report to the IRB

- Use the form ‘Report of Unanticipated Problems’ on IRBNet
- Report events that (All 3 criteria must be met)
  - Unanticipated, unforeseen or unexpected.
    - For adverse events, or clinical information, this means that this information was not available in the material available to the IRB, not in the consent documents, or not expected for this disease or condition.
  - Related to the research
    - For adverse events, this means there is a *reasonable* possibility that the adverse event or problem may have been caused by the test article (study drug/biologic/device) or research participation
  - Indicates that participants or others are at increased risk of harm

### 9.1.1. Study Coordinator REDCap Instructions for AE Reporting

In the MICT-data REDCap project

- Click ‘Add/Edit Records’ and chose the participant ID for this participant
- Click the button for ‘Adverse Events Worksheet’ under Ongoing
  - Complete the form as described above under Procedures
  - Set form as ‘Incomplete’
  - Click ‘Save’
  - You will see a popup to provide a value for
    - Was event serious (SAE)?
    - AE related to study drug or procedure?
    - Investigator will sign electronically in REDCap
  - Click “Ignore and leave record”
- Contact the physician to review the event and to complete the required questions
  - Was the event serious
  - Was the AE related to study drug or study procedures
- The physician will login to REDCap using their login and password
  - The physician will review the AE and complete the required questions
  - Instruct the physician to leave the form as “Incomplete”
  - Instruct the physician to Click “Save”

### 9.2. Serious Adverse Events

#### Purpose

- To report a serious adverse event

#### Definition

- An adverse event or suspected adverse reaction is considered “serious” if, in the view of either the investigator or sponsor, it results in any of the following outcomes:
  - death
  - a life-threatening adverse event,
  - inpatient hospitalization or prolongation of existing hospitalization

- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions,
- a congenital anomaly/birth defect
- pregnancy
- Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention (treatment) to prevent one of the outcomes listed in this definition. Examples include:
  - allergic bronchospasm requiring intensive treatment in an emergency room or at home
  - blood dyscrasias (e.g., leukemia) or convulsions that do not result in inpatient hospitalization, or
  - development of drug dependency or drug abuse

#### **When to Assess**

- Adverse events are assessed on a continual basis through the study from data collected on the Morning/Evening Reports, FaceTime appointments, onsite appointments, etc.

#### **Study Physician Role**

- Reviews SAE
- Determines severity
- Determines relatedness to study drug
- Determines medical care required
  - Continuation or discontinuation of study drug
  - Other asthma treatment

#### **Procedures**

- The Serious Adverse Events Worksheet is under the column “Ongoing”
  - All serious adverse events will be recorded on this form throughout the participant’s trial participation
- Follow the instructions on the form
- If the “Outcome of event” is “ongoing” at the time the form is completed, it can be updated to one of the other choices at a later date when an outcome is known.
  - When making changes to the “Outcome of event” from “ongoing” to another outcome choice, you must include a short explanation in the call out bubble.
    - This information will then be stored in the event history along with the person making the change
- The physician will be required to complete:
  - Severity of intensity of event
  - Relationship of adverse event to study drug (if the participant was on study drug)
  - Was adverse event related to a study procedure or the study design, other than study drug
- If there are multiple events, a second adverse event form will become available as soon as data is entered into “Adverse event name”

#### **Reporting**

- To the PI as soon as known
- Report to the IRB as described under Adverse Events (within 5 days of discovery, or within 24 hours if an unforeseen death). (**Click here to see [Adverse Events](#) section in this MOP**).

### 9.2.1. Study Coordinator REDCap Instructions for SAE Reporting

In the MICT-data REDCap project

- Click 'Add/Edit Records' and chose the participant ID for this participant
- Click the button for 'Serious Adverse Event Report' under Ongoing
  - Complete the form as described above under Procedures
  - Set form as 'Incomplete'
  - Click 'Save'
- Contact the physician to review the event and to complete the required questions
  - Severity of intensity of event
  - Relationship of adverse event to study drug (if the participant was on study drug)
  - Was adverse event related to a study procedure or the study design, other than study drug
- The physician will login to REDCap using their login and password
  - The physician will review the SAE and complete the required questions
  - Instruct the physician to leave the form as "Incomplete"
  - Instruct the physician to Click "Save"

### 9.3. Unanticipated Administrative Events

#### Purpose

- To report an event that is neither an adverse event nor serious adverse event using the *Report of Unanticipated Administrative Event* form (**Click here to see [Adverse Events](#) and [Serious Adverse Events](#) section in this MOP**).

#### Definition

- Occurrences of breaches of confidentiality, destruction of study records, unaccounted for study drug, irregularities in the randomization process, or other such problem/deviation. Some unusual events may require IRB reporting. Visits outside of window do not need to be reported.

#### Procedures

- This form is NOT saved under an individual participant's REDCap data file
  - It is stored as a general document because some reported events may relate to multiple participants
- Summarize this event using the Report of Unanticipated Administrative Event form (**Click here to go to the document [Report of Unanticipated Administrative Event](#) form**).
- Follow the instructions on the form for completing and saving the file
  - Save the document on the shared drive in your site folder. (**Click here to go to the folder to save the file [Report of Unanticipated Administrative Event](#) form**)
  - Upload the document to the REDCap file repository (**Click here for instructions on uploading the form to REDCap [Upload Instructions](#)**).

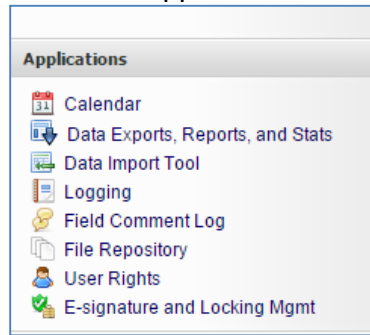
#### Reporting

- Report to the IRB as described under Adverse Events (within 5 days of discovery, or within 24 hours if an unforeseen death). (**Click here to see [Adverse Events](#) section in this MOP**).

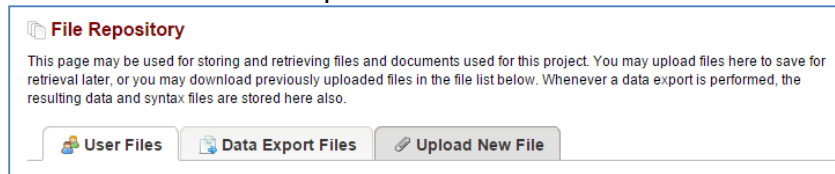
### 9.3.1. Study Coordinator REDCap Instructions for Administrative Reporting

In the MICT-data REDCap project

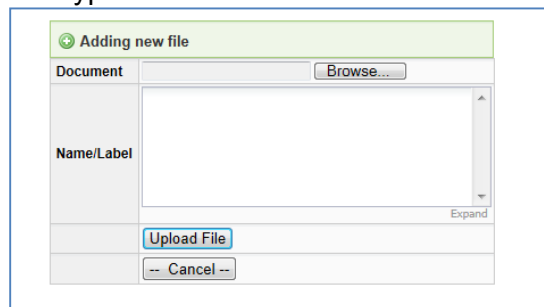
- Under Applications click on 'File Repository'



- Click to Upload New File



- Browse to the folder that has the completed form in your site folder
- Type the file name in the box 'Name/Label'



- Click 'Upload File'

## 10. Study Drug Description, Procurement, Storage

Insert info here

### 10.1. Overview

**Study Site Pharmacist (ORL and WIL) will follow institution procedures to:**

- Purchase of all study drug
- Manage center level (MICT – drug accountability by site) and participant level drug accountability (Drug Accountability Log) logs in REDCap
- Manage disposal of all returned drug

**Administrative Coordinator (for JAX, PNS, PHL)**

- Will be responsible for purchase and distribution of all study drug
  - Will distribute Advair 250/50 and ProAir to the sites to have on hand for V1
  - Will prepare and ship study drug directly to study participants
    - All shipments will be verified by a licensed nurse or pharmacist and at note will be recorded in REDCap
- Manage center level (MICT – drug accountability by site) and participant level drug

- accountability (Drug Accountability Log) logs in REDCap
  - Manage disposal of all returned drug according to Nemours policy and procedures
- Study Site Coordinator (at the JAX, PNS, PHL sites)**
- Will be responsible for completing the 'MICT – drug accountability site' form (in MICT-data project)
    - When drug is received from the JAX site (Visit 1 drug supplies of Advair 250/50 and Proair)
    - When drug is dispensed to participant at Visit 1 (Advair 250/50 and Proair)
  - Will be responsible for completing the 'Drug Accountability Log' for each participant when Advair 250/50 or Proair is dispensed at Visit 1

## 10.2. ProAir (albuterol)

### Dispensing

- 1 ProAir will be provided at Visit 1 and additional ProAir will be provided based upon usage
- REDCap will send an alert to the SC when the ProAir counter number reaches 30 or lower on the Evening Report
  - Notify pharmacist or AC that another ProAir needs to be sent
  - The amount of ProAir used can be viewed for each participant. (*Click here to see [Participant albuterol use](#) section in this MOP*).

### 10.2.1. RPh and AC (and Site Coordinator at PHL and PNS at Visit 1 only) REDCap Instructions for ProAir Drug Accountability

The Site Coordinators can view Visit 1 instructions (*Click here to see Visit 1 [Study Coordinator REDCap Instructions](#) section in this MOP – see the part about Drug Accountability*)

In the MICT-data REDCap project

- Click 'Add/Edit Records' and choose the participant ID
- Click the button for 'Drug Accountability Log' under Ongoing
- Complete this form
  - Medication dispensed
    - Under 'Medicine Dispensed' the drug for shipment/dispensing must be verified by a licensed nurse or pharmacist
      - Verify correct participant, correct drug, correct dose, correct dosing instructions, correct lot number, correct expiration date
        - enter a note in the callout button
  - Date dispensed
  - Scheduled start date
  - Lot number
  - Expiration date
  - How provided
  - Delivery status
    - If drug was FEDEXed:
      - Check the FEDEX airbill number after shipment to confirm delivery
  - Date of drug return

- Will be completed most likely at Visit 6 when the participant returns to the clinic with all the used study drug
- Set form as 'Unverified'
  - At Visit 6, after documenting all returned drug, set form as 'Complete'
- Click 'Save Record'

### 10.3. Stable-Phase Advair 250/50 (V1 and V2)

#### Dispensing

- 1 Advair 250/50 will be provided at Visit 1 and additional Advair 250/50 will be provided based upon usage or 30 days after the V1 Advair was opened from the foil pouch
  - Please try and schedule V2 FaceTime visit before the V1 Advair runs out. This is because if the participant does not meet criteria for study continuation, then we will not need to send another Advair 250/50.
  - Please try and schedule Vw FaceTime visit before the Vw Advair runs out. This is because if the participant does not meet criteria for study continuation, then we will not need to send another Advair 250/50 because they would be randomized to study drug within a few days.
- Participant Instructions
  - The SC will remind the participant that the Advair 250/50 is to be used as 1 inhalation twice daily
  - The SC will remind the participant that the Advair 250/50 takes the place of their regularly used asthma controller medication
  - The SC will inform the participant that each diskus must remain in its sealed pouch until the date indicated on the participant instruction form **((Click here to view the MICT Drug Instructions for Participant Insert form included when mailing study drug: [Study Drug Instruction Insert.](#)) - unless for some reason it needs to be started at an earlier date**
- REDCap will send an alert to the SC when the Diskus counter number reaches 14 or lower on the Evening Report
  - Notify pharmacist or AC that another Advair 250/50 needs to be sent
  - The amount of Advair 250/50 used can be viewed for each participant. **(Click here to see [Diskus use](#) section in this MOP).**

#### 10.3.1. RPh and AC (and Site Coordinator at PHL and PNS at Visit 1 only) REDCap Instructions for Stable-Phase Advair 250/50 Drug Accountability

The Site Coordinators can view Visit 1 instructions (**[Click here to see Study Coordinator REDCap Instructions](#) section in this MOP – see the part about Drug Accountability**)

In the MICT-data REDCap project

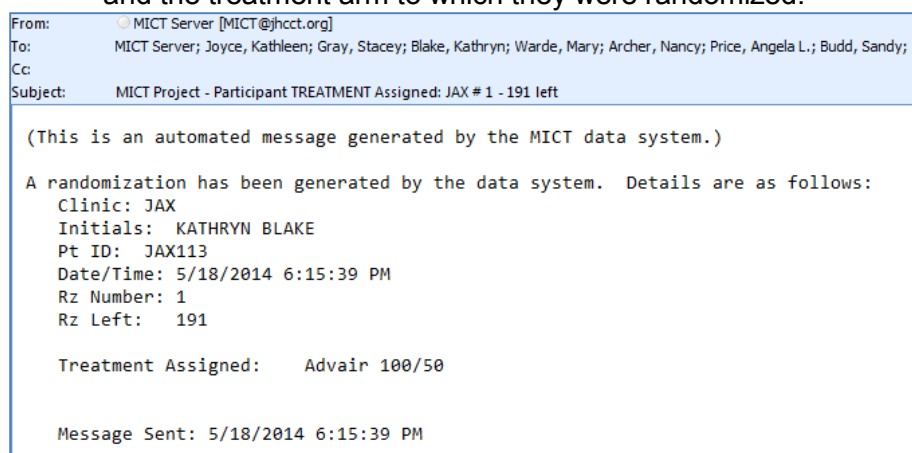
- Click 'Add/Edit Records' and choose the participant ID
- Click the button for 'Drug Accountability Log' under Ongoing
- Complete this form
  - Medication dispensed
    - Under 'Medicine Dispensed' the drug for shipment/dispensing must be verified by a licensed nurse or pharmacist
      - Verify correct participant, correct drug, correct dose, correct dosing instructions, correct lot number, correct expiration date

- enter a note in the callout button
- Date dispensed
- Scheduled start date
- Lot number
- Expiration date
- How provided
- Delivery status
  - If drug was FEDEXed:
    - Check the FEDEX airbill number after shipment to confirm delivery
- Date of drug return
  - Will be completed most likely at Visit 6 when the participant returns to the clinic with all the used study drug
- Set form as 'Unverified'
  - At Visit 6, after documenting all returned drug, set form as 'Complete'
- Click 'Save Record'

#### 10.4. Study Drug (Randomized Period) (V3, V4, V5)

##### Randomization

- The SC at each site, RPh, AC, and PI will receive an email from the MICT server when a participant is randomized. The email will identify the participant by their Participant ID and the treatment arm to which they were randomized.



##### Dispensing

- 1 study diskus will be mailed after treatment randomization has determined the study drug arm at Visit 3. Additional study diskus will be provided based upon usage or 30 days after the last study diskus was started as determined from the Morning or Evening Report "Did you start your new Diskus with this Dose?"
- REDCap will send an alert to the SC when the Diskus counter number reaches 14 or lower on the Evening Report
  - Notify pharmacist or AC that another study diskus needs to be sent
  - The amount of study diskus used can be viewed for each participant. **(Click here to see [Diskus use](#) section in this MOP).**
  - The SC will inform the participant that each diskus must remain in its sealed pouch until the date indicated on the participant instruction form **(Click here to view the MICT Drug Instructions for Participant Insert form included when mailing study drug: [Study Drug Instruction Insert.](#))** - unless for some reason it



needs to be started at an earlier date

Advair 250/50 Diskus	The device should be discarded 1 month after removal from the moisture-protective foil overwrap pouch or after all blisters have been used (when the dose indicator reads “0”), whichever comes first. Do not attempt to take the device apart.
Advair 100/50 Diskus	The device should be discarded 1 month after removal from the moisture-protective foil overwrap pouch or after all blisters have been used (when the dose indicator reads “0”), whichever comes first. Do not attempt to take the device apart.
Flovent 250 Diskus	FLOVENT DISKUS should be discarded 6 weeks (50-mcg strength) or 2 months (100- and 250-mcg strengths) after removal from the moisture-protective foil pouch or after all blisters have been used (when the dose indicator reads “0”), whichever comes first. Do not attempt to take the device apart.

### Treatment Arms

There are 3 study arms for randomized drug treatment

- Advair 250/50 – 1 inhalation twice daily
- Advair 100/50 – 1 inhalation twice daily
- Flovent 250 – 1 inhalation twice daily

#### 10.4.1. RPh and AC REDCap Instructions for Study Diskus (Randomized Period) Accountability

In the MICT-data REDCap project

- Click ‘Add/Edit Records’ and chose the participant ID
- Click the button for ‘Drug Accountability Log” under Ongoing
- Complete this form
  - Medication dispensed
    - Under ‘Medicine Dispensed’ the drug for shipment/dispensing must be verified by a licensed nurse or pharmacist
      - Verify correct participant, correct drug, correct dose, correct dosing instructions, correct lot number, correct expiration date
        - enter a note in the callout button
  - Date dispensed
  - Scheduled start date
  - Lot number
  - Expiration date
  - How provided
  - Delivery status
    - If drug was FEDEXed:
      - Check the FEDEX airbill number after shipment to confirm delivery
  - Date of drug return
    - Will be completed most likely at Visit 6 when the participant returns to the clinic with all the used study drug
- Set form as ‘Unverified’
  - At Visit 6, after documenting all returned drug, set form as ‘Complete’

- Click 'Save Record'

## 10.5. Procurement, Receipt, and Storage of Drug

### Procurement

- ORL and WIL pharmacists will order drug to have in stock
  - Suggest keeping minimal drug in stock to avoid drug expiring before it has been dispensed
- AC will order drug for JAX, PNS, and PHL
  - Stable phase Advair 250/50 and ProAir will be shipped to PNS and PHL so that the sites have some on hand for V1
  - Randomized drug treatment will be mailed directly to the participant by the RPh at ORL and WIL and by the AC for JAX, PNS, PHL

### Receipt

- ORL and WIL pharmacists will maintain center and participant drug accountability logs on REDCap
- AC will maintain center and participant drug accountability logs on REDCap for JAX, PNS, PHL

### Storage

- ProAir
  - Store at controlled room temperature, 59° to 77° F
- Advair and Flovent
  - Store at controlled room temperature, 68° to 77° F

### 10.5.1. RPh and AC (and Site Coordinator at PHL and PNS) REDCap Instructions for Study Procurement/Receipt Accountability

These steps are to be completed anytime drug is received or dispensed by the pharmacy (in ORL and WIL) or by the study sites from JAX

### Center Level Drug Accountability Log

In the MICT-drug accountability by site REDCap project

- To enter data (when receiving drug)
  - Click 'Add/Edit Records' and click 'Add new record'
  - Complete the 'Drug Accountability Log' form
    - Select/record Study Site location
    - Select medication
      - Advair 250/50 (60blister/Diskus), Advair 100/50mcg Diskus (60 blisters), Flovent 250mcg Diskus (60 blisters) or ProAir 90 mcg/actuation 8.5g
    - Select manufacturer
    - Enter Lot Number
    - Enter expiration date from the package
    - Enter number of Diskus in this transaction
    - Select "received" or "dispensed"
      - For "received", select appropriate choice (site or manufacturer)
    - Enter remaining balance at the site
    - Add any relevant notes
      - E.g. whether Advair is for run-in or randomization
  - Set status to 'Ccomplete'

- Click 'Save' or click 'Save and Continue' if creating a pdf for the transaction
    - Start a new record for each receipt/dispense of study drug
- To view a report of transactions for a single medication (e.g. Proair, Advair 250/50, randomized drug)
  - Click on the name of the report in the left panel under 'Reports'
    - To print report, click 'Print page'
    - To download report as an Excel file, click 'Microsoft Excel (CVS)'
- To create a pdf file of a single transaction
  - Enter a record by doing one of the following:
    - Click 'Add/Edit Records' and select the records from the drop-down list.
    - Click on the Entry ID in a report of transactions
    - Click 'Save and Continue' after entering data
  - Click the 'Download PDF of instrument(s)' button
  - Select 'This data entry form with saved data'
  - Click the radio button next to 'Save File'
  - Click OK

Repeat the steps above for all drugs when received (ProAir, Advair 250/50, Advair 100/50, Flovent 250)

## 10.6. Labeling and Shipment Information

### Information Included on Study Drug Label

- ORL and WIL pharmacists will label drug according to state law and Nemours policy
- AC will label drug according to state law and Nemours policy for JAX, PNS, and PHL
  - Labels for drug can be viewed in the Administrative Logs folder (***Click here to view the MICT Drug Instructions for Participant Insert form included when mailing study drug: [Study Drug Labels.](#)***)
  - Note that the drug label for JAX, PNS, and PHL does not include the Lot number or Expiration date as this information is on the drug product itself

### Information Included on Study Drug Shipment

- Participant instructions for study drug use are included in the shipment box to the participant. (***Click here to view the MICT Drug Instructions for Participant Insert form included when mailing study drug: [Study Drug Instruction Insert.](#)***) - unless for some reason it needs to be started at an earlier date

### FEDEX Study Drug Shipment

- FEDEX is used to ship the drug directly from the pharmacy at ORL and WIL and from the JAX site for JAX, PFN, and PHL
- A copy of the tracking receipt can be found in MICT-data REDCap project Drug Accountability Log

## 10.7. Accountability Logs in REDCap

### Purpose

- To manage drug accountability both at the participant level and center level

### Procedures

- Participant Level Drug Accountability Log
  - ***Click here to see ProAir section [Participant Level ProAir REDCap Instructions](#) in this MOP).***
  - ***Click here to see Stable Phase Advair 250/50 REDCap section [Participant](#)***

- [Level Stable Phase Advair 250/50 REDCap Instructions in this MOP\).](#)
  - [Click here to see Randomized Drug REDCap section RPh and AC REDCap Instructions for Study Diskus \(Randomized Period\) Accountability in this MOP\).](#)
- Center Level Drug Accountability Log
  - [Click here to see Center Level Drug Accountability section Study Procurement/Receipt REDCap Instructions in this MOP\).](#)

## 10.8. Temporary Withdrawal or Termination of Study Drug

### Definition

- Study treatment drug refers to the drug randomly assigned to the participant

### Purpose

- To set criteria for the temporary withdrawal or termination of study drug administration

### When

- Any time after completion of randomization visit (V3) when study drug is temporarily or permanently stopped due to adverse event, participant request, lost to follow-up, pregnancy, or other reason
- At end of study (completion of V6)

### Tasks

- Unscheduled temporary study drug termination
  - Record information relating to the hiatus in study on the next Clinic Visit form for the upcoming visit in REDCap
  - Record a note in the Notes field of the Diary Card for the date that the participant stopped taking the drug ([Click here to see Participant Morning or Evening Report editing section in this MOP.](#))
  - Complete the Adverse Event, Serious Adverse Event or Unanticipated Administrative Event form as appropriate
- Unscheduled permanent study drug termination before end of study
  - If participant experiences moderate or severe side effects, the Study Physician will:
    - Evaluate severity of symptoms as rated by participant
    - Decide if side effects are suspected to be related to study drug
    - Determine if study drug should be terminated
  - Complete the Adverse Event, Serious Adverse Event or Unanticipated Administrative Event form as appropriate
  - Complete Treatment Termination form in REDCap
  - Collect all study treatment diskuses (including any unused study diskus) from participant
  - Complete Drug Dispensing and Counting (DD) form
  - Continue to follow participant for all study visits (i.e., continue all relevant study procedures) through V6

## 11. REDCap Troubleshooting


### 11.1. Instructions for Participants Temporarily Without Internet Access

Participant may relay Diary Report data to Clinical Coordinator via text, email or phone call.

Enter data into MICT-diary cards REDCap project

The ID for the records in this project has the format, 'participant ID\_date'. The format of the date must be YYYY-MM-DD and the letters must be uppercase. Here is an example ID. JAX105\_2013-01-05. (This date is January 5, 2013.)

- Click 'Add/Edit Records'
- If the participant has submitted either a morning card or evening card for the day to be altered, choose the record.
- If the participant has not submitted anything for the day, a new record will need to be created.
  - Enter a new record using the format above and hit the 'Enter' key on the keyboard. Make sure you put the ID in the "Enter a new or existing..." box and not in the box in the "Data Search" section (see below).

 **Day**

You may view an existing record/response by selecting it from one of the drop-down lists below. The records each drop-down list according to their status for this particular data collection instrument. To create a new record, enter a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, populate with existing record names as you begin to type in it, allowing you to select it.

<b>Total records: 655</b>	
<b>Incomplete Records (654)</b>	-- select record --
<b>Complete Records (1)</b>	-- select record --
<b>Enter a new or existing Record</b> This is the primary key for this project. It is created using the participant ID and date for the submission.	<input type="text" value="JAX190_2015-03-29"/>

[Show](#)

**Data Search**

<b>Choose a field to search</b> <small>(excludes multiple choice fields)</small>	-- select search field --
<b>Search query</b> <small>Begin typing to search the project data, then click an item in the list to navigate to that record.</small>	<input type="text"/>

- Enter data into the fields in the form 'Day' if they are empty. Edit any data that the participant has entered incorrectly. Enter notes for any field by clicking the dialog symbol next to the data entry box, type your comments and click 'Comment'. Click 'Save and go to the Next Form' if you added or changed any data. If the form was already filled out and you didn't change any data, click the dot next to 'Morning' in the left side panel.
- Enter data into the fields in the form 'Morning' if they are empty. Edit any data that the participant has entered incorrectly. Enter notes for any field by clicking the dialog symbol next to the data entry box, type your comments and click 'Comment'. Click 'Save and go to the Next Form' if you added or changed any data. If the form was already filled out, click the dot next to 'Evening' in the left side panel.
- Enter data into the fields in the form 'Evening' if they are empty. Edit any data that the

participant has entered incorrectly. Enter notes for any field by clicking the dialog symbol next to the data entry box, type your comments and click 'Comment'. Click 'Save and go to the Next Form' if you added or changed any data. If the form was already filled out, click the dot next to 'Notes' in the left side panel.

- Enter your notes into the textbox on this form.
- Set the form as 'Complete'.
- Click 'Save'

If the date/timestamp for submission of the morning and/or evening diary card was blank when data was entered into the MICT-diary cards REDCap project in the steps above, go to the MICT-DC summary REDCap project.

View report called 'data'.

- In left sidebar under 'Reports', click the link called 'data'
  - Find data for the participant, then look for the first day of the week (far right of the table) for which you entered diary card data.

Participant ID (participant_id)	Event Name (redcap_event_name)	CTPayer account (ctpayer)	Number of days in this week. Assume weeks run from Sunday to Saturday. (days_in_wk)	Total number of morning cards completed in the week. (morning_sum)	Total number of evening cards completed in the week. (evening_sum)	Total number of morning and evening cards submitted. (diary_total)	First day of the week (date_diarywk)
24a Harrison, William	Ongoing	23434557568568					
24a Harrison, William	14th wk		7	0	0	0	10-06-2014
25	4th wk		7	0	0	0	07-15-

- If data for the week is not in the table yet, do nothing more.
- If data for the week is in the table, note which Event Name the week is assigned.
  - Click the participant ID in the report. This will take you to the event grid.

Event Grid																
<p>The grid below displays the form-by-form progress of data entered into the project for one particular Participant ID for all defined events. You may click on the colored buttons to access that form for that event. If you wish, you may modify the events below by navigating to the <a href="#">Define My Events</a> page.</p>																
<p>Participant ID <b>24a</b> Harrison, William</p>																
Data Collection Instrument	Ongoing (1)	1st wk (2)	2nd wk (3)	3rd wk (4)	4th wk (5)	5th wk (6)	6th wk (7)	7th wk (8)	8th wk (9)	9th wk (10)	10th wk (11)	11th wk (12)	12th wk (13)	13th wk (14)	14th wk (15)	15th wk (16)
Participant ID																
Participant Information																
Clinic Visits, FaceTime Visits, Satisfaction Survey																
Diary Card Submission Summary																

- 
- 

- Then enter the 'Diary Card Submission Summary' for the appropriate event.

**Diary Card Submission Summary**

Editing existing Participant ID **24a** Harrison, William

Event Name: **14th wk**

Participant ID 24a

First day of the week 10-06-2014 Today M-D-Y  
This field is completed by computer code.

Number of days in this week. Assume weeks run from Sunday to Saturday. If the participant starts on Friday, then first week would have 2 days. 7  
days - This field is completed by computer code.

Total number of morning cards completed in the week. 0  
This field is completed by computer code.

Total number of evening cards completed in the week. 0  
This field is completed by computer code.

Total of number of morning and evening cards submitted. 0  
This field is completed by computer code.

Credit for this week added to card. ☐ Yes ☐ No

Most recent date that credit was added to card.  Today M-D-Y

Notes

- - If credit for this week has already been added to the CTPayer card, contact the Administrative Coordinator.
  - If credit for this week has not been added to the CTPayer card
    - Enter the appropriate data.
    - Click 'Save Record'.

## 11.2. Correcting Entry when Diskus Started but not Indicated on Diary Report

If a new Diskus was started and not indicated in a diary report submission by the participant

- Record this in the MICT-diary cards REDCap project as described above (**Click here to see [Enter data into MICT-diary cards REDCap project](#) section in this MOP.**)
  - The field, 'Expected counter number on Diskus', will not be updated automatically. If there as any data in this field after the date the new Diskus was started, the Clinical Coordinator must either manually deleted the incorrect data or manually replace the incorrect values with correct values.
    - To see the data that has been entered for 'Expected counter number on Diskus', click on 'Diskus counter' under Reports in the left side. Then scroll to the records for the appropriate participant.
- Record the date the new Diskus was started in the MICT-data REDCap project
  - In the MICT-data REDCap project, click 'Add/Edit Records' and choose the participant
  - Click on the dot in the grid for the 'Drug Accountability Log' under the event 'Ongoing'.
  - Enter the date the new Diskus was started into the field 'Most recent date a new study Diskus was started' at the top of the form.
  - Enter notes by clicking the dialog symbol next to the data entry box, type your comments and click 'Comment'.
  - Click 'Save Record'



### 11.3. Missing and/or Re-sending Questionnaires to Participants

#### Asthma Control Test

The participant needs to complete the ACT in one sitting. You can provide them with a link to the questionnaire from within REDCap.

In the MICT-data REDCap project:

- Click 'Add/Edit Records' and choose the participant ID for this participant
- Click on the dot in the grid for the Asthma Control Test under the appropriate event
- Click on the 'Compose survey invitation' button, this will pop up a template for an email message
  - Select the participant's study email address from the dropdown list next to 'To:'
  - Type a subject line for the message. This can be something like "Link to the Asthma Control Test"
  - Type a message into the box and click 'Send Email'. Your message will be in the body of the email that is sent. The following text will follow your message:

"You may open the survey in your web browser by clicking the link below:

Use of Mobile Devices and the Internet to Streamline An Asthma Clinical Trial **Asthma Control Test™**

If the link above does not work, try copying the link below into your web browser:

<https://apps.nemoursresearch.org/redcap/surveys/?s=XXXXXXXXX>

This link is unique to you and should not be forwarded to others.

#### Baseline Asthma and Medical History

If the participant loses the email with instructions to complete this questionnaire, you can provide them with the following link:

[https://apps.nemoursresearch.org/mict/BA\\_home.php](https://apps.nemoursresearch.org/mict/BA_home.php)

If they are not already logged into the Asthma Research Study website, they will be prompted to log in before they can see the questionnaire.

The Baseline Asthma and Medical History questionnaire does not need to be completed in one sitting. To stop and come back at another time, click the 'Save and Exit' button at the bottom of the page. When the participant is ready to go back to this questionnaire, you can provide them with the following link:

[https://apps.nemoursresearch.org/mict/BA\\_home.php](https://apps.nemoursresearch.org/mict/BA_home.php)

If they are not already logged into the Asthma Research Study website, they will be prompted to log in before they can see the questionnaire.

#### EQ-5D

The participant needs to complete the EQ-5D in one sitting. If the participant loses the email with instructions to complete this questionnaire, you can provide them with the following link:

<https://apps.nemoursresearch.org/mict/eq5d-eq.php>

If they are not already logged into the Asthma Research Study website, they will be prompted to log in before they can see the questionnaire.

If the participant is given the message “You don’t have an upcoming visit within 4 days.”, check the scheduled visit date and actual visit date that are recorded in REDCap.

If this is for Visit 6 – Part 2 (i.e. they need to complete the EQ-5D while at the clinic) because they did not complete the EQ-5D for Visit 6 – Part 1 (FaceTime), then follow the below instructions for changing the **Scheduled visit date and time** in Visit Dates Visit 6 Virtual. Make sure you pick a time that is a future time (for example, if the visit is at 3PM pick a time for the visit at 6PM) You will need to delete the **Actual Visit Date** in Visit Dates Visit 6 Virtual also per the instructions below. When you are done, go back and re-enter the correct **Actual Visit Date** in the Visit 6 Virtual. Put a note in the comments field as to why you did this (because it will be tracked in the history field).

In the MICT-data REDCap project:

- Click ‘Add/Edit Records’ and choose the participant ID for this participant.
- Click on the dot in the Event Grid for ‘Visit Dates’ under the appropriate event.
- Any date can be entered for **Target date**.
- Check the **Scheduled visit date and time**.
  - If this is incorrect, enter the correct date.
  - This questionnaire is available 4 days before the **Scheduled visit date**, up to and including the **Scheduled visit date**.
- Check the **Actual visit date**
  - This field should be left blank. If this has a date, delete the date.
- Click ‘Save Record’
- After participant completes the EQ-5D, enter and save the **Actual visit date**.

Eligibility Questionnaire (aka Screening Form), Children’s Health Survey, Quality of Life Questionnaires, and Pre-Clinic Visit Questionnaire (aka Clinic Visit form)

If the participant loses the email with instructions to complete this questionnaire and **has not started** the survey, you can provide them with a link to the survey via email from within REDCap.

In the MICT-data REDCap project:

- Click ‘Add/Edit Records’ and choose the participant ID for this participant
- Click on the dot in the Event Grid for the appropriate survey and event
- Click on the ‘Compose survey invitation’ button, this will pop up a template for an email message
  - Select the participant’s study email address from the dropdown list next to ‘To:’.
  - Insert a subject line for the message. This can be something like “Link to Asthma Study questionnaire”
  - Insert a brief message to the participant and click ‘Send Email’. Your message will be in the body of the email that is sent. The following text will follow your message.
 

“You may open the survey in your web browser by clicking the link below:

```
<div style="font-size:16px">Use of Mobile Devices and the Internet to Streamline An Asthma Clinical Trial</div><br /><br /><div align="center"><b>Asthma Control Test™</b></div>
```

If the link above does not work, try copying the link below into your web browser:

<https://apps.nemoursresearch.org/redcap/surveys/?s=XXXXXXXX>

This link is unique to you and should not be forwarded to others.

- A link to the questionnaire will be automatically included in the message.
- Click 'Send Email'

If a participant clicks the 'Save & Return Later' button on a REDCap survey (Eligibility (Screening Form), Children's Health Survey, Quality of Life Questionnaires, or Pre-clinic visit (Clinic Visit)) and **has trouble returning to the survey**, you can provide them with a link to the survey and the Return Code via email from within REDCap.

In the MICT-data REDCap project:

- Click 'Add/Edit Records' and choose the participant ID for this participant
- Enter the Participant Information form
- Copy the study email address
- Click on the Participant ID in the left sidebar to return to the Event Grid
- Click on the dot in the grid for the appropriate survey and event
- Click on the 'Email survey link' button, this will pop up a template for an email message
  - Paste the study email address in the To: section of the message
  - Delete the following sentence from the message "A survey admin can provide you with a validation code so that you may complete the survey from where you left off."
  - Insert a sentence that contains the Return Code, like the following:  
 "After you follow this link, enter this code into the web page:  
*SC or AC should paste Return Code here*"
- Click 'Send Email'

**Sending email invitations for participants to complete the Screening form (aka Eligibility Questionnaire), ACT, Children's Health Survey for Asthma or Quality of Life Questionnaires for the events Unscheduled1, Unscheduled2, Unscheduled3, Unscheduled4 or Unscheduled5**

In the MICT-data REDCap project:

- Click 'Add/Edit Records' and choose the participant ID for this participant
- Click on the Participant ID in the left sidebar to return to the Event Grid
- Click on the dot in the Event Grid for the appropriate survey and event
- Click on the 'Compose survey invitation' button, this will pop up a template for an email message
  - Specify when the message should be sent.
  - Select the participant's study email address from the dropdown list next to 'To:'.
  - Insert a subject line for the message.
  - Insert a brief message to the participant and click 'Send Email'. Your message will be in the body of the email that is sent.
  - A link to the questionnaire will automatically be included in the message that is sent.
- Click 'Send Email'

**To send email invitations to a participant for the additional Screening form, ACT or Children's Health Survey for Asthma with text approved by the IRB automatically.**

In the MICT-data REDCap project:

- Click 'Add/Edit Records' and choose the participant ID for this participant.
- Click on the dot for 'Send Additional Surveys' under Screening.
- Set the field that you want to send an invitation for to Yes.
- Set the form status as 'Unverified'.
- Click 'Save Record'
  - The email invitation will be sent immediately.

**To send email invitations to a participant or parent for the End of Study Satisfaction Survey. (AC)**

The messages are sent to [AsthmaResearch@nemours.org](mailto:AsthmaResearch@nemours.org) when they are originally sent to the participant and parent. The messages to the participant and the participant each have a link to the appropriate survey. If these messages are available, they can be sent to the appropriate email addresses. If these messages are not available do the following:

- In the MICT-data REDCap project:
- Click 'Add/Edit Records' and choose the participant ID for this participant.
  - Click on the dot for 'Parent End Satisfaction-MICT' under Visit6-clinic.
  - Click 'Survey options' and then 'Compose survey invitation'.
  - In the 'Compose message' section:
    - Choose 'AsthmaResearch@nemours.org' for 'From'.
    - Enter the parent's email address next to 'Or provide another email:'
    - Enter "End of Study Satisfaction Questionnaire to complete – for the Parent" next to 'Subject:'
    - Enter the following for the content of the message

Dear [Parent\_First\_Name Parent\_Last\_Name],

Thank you for your participation in this Asthma Research Study. Now that your child has completed the study, we would like you, the parent, to complete a questionnaire to tell us about your experience in the study. Please complete the End of Study Satisfaction Questionnaire as soon as you can within the next 5 days. We will send you a \$10 Walmart gift card upon return of the questionnaire.

This questionnaire will take approximately 10 minutes.

If you have any questions, or if you'd like to speak with someone right away, call:

800-767-5437 extension 55-3925

Or

904-697-3925

You can also send an email to [asthmaresearch@nemours.org](mailto:asthmaresearch@nemours.org).

Thank you for your participation in this study.

The Nemours Asthma Study Staff

- Click 'Send Invitation'
- Click on the dot for 'Youth End Satisfaction – MICT' under Visit6-clinic.
- Click 'Survey options' and then 'Compose survey invitation'
- In the 'Compose message' section:
  - Choose 'AsthmaResearch@nemours.org' for 'From'.
  - Enter the participant's email address next to 'Or provide another email:'
  - Enter "End of Study Satisfaction Questionnaire to complete – for the Adolescent" next to 'Subject:'
  - Enter the following for the content of the message

Dear [Participant\_First\_Name Participant\_Last\_Name]

Thank you for your participation in this Asthma Research Study. Now that you have completed the study, we would like you to complete a questionnaire to tell us about your experience in the study. Please complete the End of Study Satisfaction Questionnaire as soon as you can within the next 5 days. We will send you a \$10 study MasterCard upon return of the questionnaire.

This questionnaire will take approximately 10 minutes.

If you have any questions, or if you'd like to speak with someone right away, call:

800-767-5437 extension 55-3925

Or

904-697-3925

You can also send an email to [asthmaresearch@nemours.org](mailto:asthmaresearch@nemours.org).

Thank you for your participation in this study.

The Nemours Asthma Study Staff

- Click 'Send Invitation'

## 12. REDCap Entries for LASST Participants

**When potential participant has been identified and randomized to LASST arm, do the following:**

- In the MICT-data REDCap project,
  - Click 'Add/Edit Records', choose the LASST arm and enter the LASST ID as the participant ID.
  - Enter data into 'Patient Screening Log' form
    - 3 fields in this form may be left blank initially, these are

- Main reason failed screen or not enrolled
  - Successfully completed V1 (enrolled)
  - Notes
- Set form status as 'Unverified' if proceeding to consent process
- Set form status as 'Complete' if failed screen
- Click 'Save Record'
- Enter data into 'Study Information' form
  - Enter the ID used to randomize the participant to the LASST arm if the participant was randomized. If the participant was not randomized, leave this field blank.
  - Do not answer 'Send email invitation for consent Satisfaction Survey for the LASST arm?' until an email address has been entered in the Participant Information form.
  - Set form status as 'unverified'
  - Click 'Save and go to Next Form'
- Enter data into all fields of 'Participant Information' form
  - Enter the PARENT'S PERSONAL email address into the 'study' email address field. This will be used to send an email invitation for the consent Satisfaction Survey (LASST version).
  - Mark form as 'complete'
  - Click 'Save Record'

**When the participant has consented, send an email invitation to complete the Satisfaction Survey by doing the following:**

- In the MICT-data REDCap project,
  - Click 'Add/Edit Records', choose the LASST arm and then choose the participant ID.
  - Click the button for 'Study Information'
  - Click 'Yes' for the field 'Send email invitation for Satisfaction Survey for the LASST arm?'
    - The parent's email address should appear in red text. To change this email address, edit the study email address entry in the Participant Information form before continuing with these steps.
  - Set form status as 'Complete'
  - Click 'Save Record'

**When the participant has returned the Satisfaction Survey the AC will send a \$10 Walmart gift card.**

**When Research Assessment and Newest Vital Sign have been administered during Visit 1, do the following:**

- In the MICT-data REDCap project,
  - Click 'Add/Edit Records', choose the LASST arm and then choose the participant ID.
  - Enter data into 'Research Assessment Interview' form under Visit1
    - Set form status as 'Complete'
    - Click 'Save Record'

Enter data into the 'Baseline Asthma and Medical History – participant version' form under Visit 1.

Obtain the ethnicity and race data from the ACRC database  
Set form status as 'Complete'  
Click 'Save Record'.

**When the participant has completed the study, send email invitations for the participant and parent to complete the End of Study Satisfaction Surveys by doing the following:**

- In the MICT-data REDCap project,
  - Click 'Add/Edit Records', choose the LASST arm and then choose the participant ID.
  - Click the button for 'Study Information'
  - Click 'Yes' for the field 'Send email invitations for the End of Study Satisfaction Survey for the LASST arm?'
    - The parent's email address should appear in red text. To change this email address, edit the study email address entry in the Participant Information form before continuing with these steps.
  - Set form status as 'Complete'
  - Click 'Save Record'
    - Two messages will be sent to the parent's email address. One will be addressed to the adolescent and one will be addressed to the parent.

## 13. Research Assessment Interview Ratings

**REDCap steps for psychologists rating of Research Assessment interviews (both MICT and ancillary LASST arms).**

In the MICT-data REDCap project

- Form names with AT are for Alex Taylor to record her ratings
- Form names with HA are for Holly Antal to record her ratings
- For each participant, there are 4 forms for collecting ratings
  - 2 for the child
    - one for AT
    - one for HA
  - 2 for the caregiver (parent/guardian)
    - one for AT
    - one for HA
- Each form should be completed for 2 events (or visits)
  - Visit1 for both MICT and LASST
  - Visit6-virtual for MICT or Visit6 for LASST
- Click 'Add/Edit Records' and choose the participant ID for this participant
- Click the button for the appropriate form under the appropriate event
  - Complete the Research Assessment form
  - Set form as 'Complete'
  - Click 'Save Record'
- Click the button for another form and repeat until all the Research Assessment forms are completed.
- To choose another participant ID, click 'Add/Edit Records' in the left sidebar.

NOTE: When choosing a participant, the list of participants in the dropdown box is for



the MICT arm by default. Change this to a list of participants for the LASST arm by clicking the dropdown box next to 'Arm 1: MICT' and choose 'Arm 2:LASST'.

## 14. Participant Stipends (CT Payer)

### Overview

- Participant stipends are paid using the CT Payer system ([www.ctpayer.com](http://www.ctpayer.com))
- CT Payer offers anonymous, reloadable, prepaid cards (Mastercard with the Nemours logo) for patient stipends and reimbursements along with personalized, reloadable, prepaid debit cards



### Process for Paying Participants

- The AC loads all cards with payments for all study sites
- Cards are loaded with \$25 after each onsite and FaceTime visit
  - The AC determines when a study visit has occurred by monitoring REDCap
- Participants receive \$1 for each Report (Morning or Evening) entered
  - The AC tallies the number of data entries every two weeks
  - Cards are loaded on Mondays
  - If there needs to be manual adjustments for Report payments (eg the participant was without internet access but did keep paper records), notify the AC and an adjustment will be made

#### 14.1. Making purchases online using CT Payer cards

Participants can may purchases online using their CT Payer cards.

Participants may want to make purchases on iTunes using their CT Payer card. To make a purchase, the participant will need the following information.

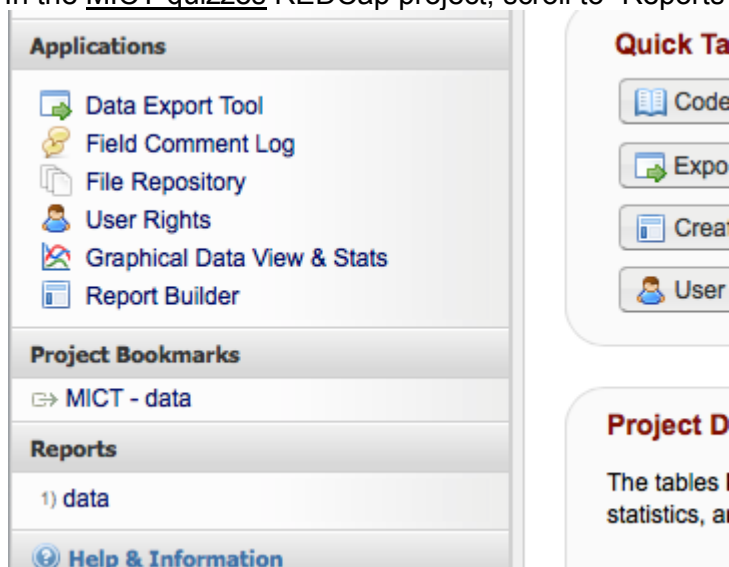
- **Birthday:** January 1970; for the day, use the last 2 digits in the UserName
  - Example micto131 would have a birthday of January 31, 1970
  - If the UserName last two digits are 32 or higher, then the birthday will just be the final digit. For example micto132 would have a birthday of January 2, 1970.
    - Apple won't let an invalid birthdate be entered so January 32, 1970 would not be valid
- **First Name:** Asthma
- **Last Name:** Study
- **Email address:** the participants gmail address
  - <UserName>@gmail.com
  - Example [mictj108@gmail.com](mailto:mictj108@gmail.com);
- **Password:** initial password assigned to participant (*Click here to see [Participant gmail and password](#) section in this MOP*).
- **Security Questions:**

- Name of first pet: Spot
- Favorite children's book: Hobbit
- Favorite sports team: Eagles

## 15. Ways to View Data on Participants in REDCap

### 15.1. Did my Participant View the Consent Video?

In the MICT-quizzes REDCap project, scroll to "Reports" and click on "data"



You will see all the participants so you will need to scroll down to find yours. They are listed by Participant ID.

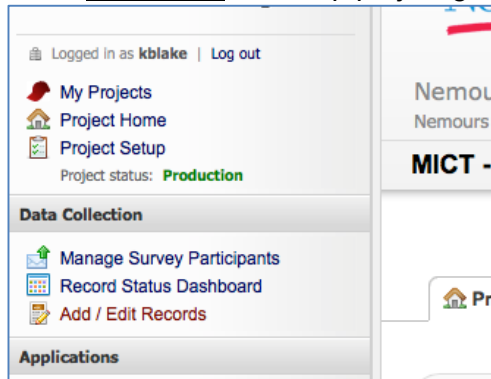
Record ID This is the primary key for this project. It is created using the participant ID and datetime stamp (in seconds beginning with January 1st). (record_id)	Participant ID (participant_id)	Date question was answered. (answer_date)	Question number As defined in mysql database mictQuiz (1-12). Except, 99 records who was present when first entering the Consent pages for each visit. (quest_num)	Correct answer This will be a letter from a-e or True or False. There is no correct answer for question 99. (cor_answer)	Answer given This will be a letter from a-e or True or False. For question 99, this will be text. (partic_ans)
<a href="#">JAX102_1382654903</a>	JAX102	2013-10-24	99	N/A	parent/guardian;child;
<a href="#">JAX102_1382655221</a>	JAX102	2013-10-24	1	e	e
<a href="#">JAX102_1382655234</a>	JAX102	2013-10-24	2	True	True
<a href="#">JAX102_1382655253</a>	JAX102	2013-10-24	3	d	d
<a href="#">JAX102_1382663476</a>	JAX102	2013-10-24	4	True	True
<a href="#">JAX102_1382663506</a>	JAX102	2013-10-24	5	e	e
<a href="#">JAX102_1382663520</a>	JAX102	2013-10-24	6	False	False
<a href="#">JAX102_1382663761</a>	JAX102	2013-10-24	7	c	c
<a href="#">JAX102_1382663784</a>	JAX102	2013-10-24	8	True	True
<a href="#">JAX102_1382663899</a>	JAX102	2013-10-24	9	True	True
<a href="#">JAX102_1382663918</a>	JAX102	2013-10-24	10	False	False
<a href="#">JAX102_1382664079</a>	JAX102	2013-10-24	11	True	True
<a href="#">JAX102_1382664095</a>	JAX102	2013-10-24	12	True	True
<a href="#">JAX102_1387815309</a>	JAX102	2013-12-23	studyStaffBtn	N/A	highslide

- 99 means that they started watching the video and for JAX102 it was watched by the parent and child.
- 1-12 are the quiz questions (there are 12 questions on the video). You can see which ones they got right and wrong.
- The long number of digits to the right of the Participant ID are date/time stamps (in seconds). If you want to find out how long they spend watching the video, you can subtract the value for question 99 (start) from the value for question 12 (finish). For

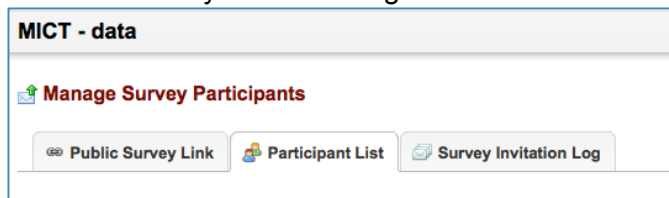
example  $1382664095 - 1382654903 = 9192$  seconds = 153 minutes.

## 15.2. Did my Participant Receive the Emails with the Links to the Questionnaires?

In the MICT-data REDCap project go to “Data Collection” select “Manage Survey Participants”:



Click on “Survey Invitation Log”:



You can see the emails sent and if the participant has responded. You can click on the “view email” to see actual email sent.

Survey Invitation Log							
(in descending order by time sent)							
Displaying <input type="text" value="1 - 50"/> of 115 Begin time: <input type="text"/> End time: <input type="text" value="05/23/2014 23:59"/> (M/D/Y H:M) Display <input type="text" value="All invitation types"/> and <input type="text" value="All response statuses"/> Display <input type="text" value="All surveys"/> <input type="button" value="Apply filters"/> <input type="button" value="Reset"/>							
Invitation send time	View Email	Participant Email	Participant Identifier	Survey	Survey Link	Responded?	Er
05/23/2014 4:00am		mictj101@gmail.com		<div style="font-size:16px">Use of Mobile Visit3-virtual (Arm 1: MICT)	-		
05/23/2014 4:00am		mictj101@gmail.com		<div style="font-size:16px">Use of Mobile Visit3-virtual (Arm 1: MICT)	-		
05/23/2014 4:00am		mictj101@gmail.com		<div style="font-size:16px">Use of Mobile Visit3-virtual (Arm 1: MICT)	-		
05/21/2014 12:00pm		micto111@gmail.com		<div style="font-size:16px">Use of Mobile Unscheduled1 (Arm 1: MICT)	-		
05/19/2014 4:00am		mictu101@gmail.com		<div style="font-size:16px">Use of Mobile	-		

To resend surveys: Click here to see "[Missing and/or Re-sending Questionnaires to Participants](#)" section in this MOP.

### 15.3. My participant has not completed all the questionnaires for Visit 1

Try and contact them to complete all the questionnaires before they come in. If they arrive for the appointment and some questionnaires need to be completed, then follow these steps:

- Make sure that REDCap has that the consents have been signed. The AC does this but recommend checking this as a first step.
  - In the MICT-data REDCap project
    - Click 'Add/Edit Records' and chose the participant ID for this participant
    - Look in the Screening column
    - Click on 'Signed Consent'
    - Make sure 'Successfully completed consent process' is "yes" and saved.

Event Name: <b>Screening (Arm 1: MICT)</b>	
Participant ID	JAX128
Successfully completed consent process.	<input checked="" type="radio"/> Yes <input type="radio"/> No
<small>reset</small> <small>This must be 'yes' for access to trial web site. (Visit 1 date must also be entered.)</small>	

- Determine which questionnaires have not been completed. You can view this in MICT-data REDCap project under Visit 1.
  - If either the "Baseline Asthma and Medical History - participant version" and "EQ-5D" has not been completed then the participants will need to do these steps first
    - In the MICT-data REDCap project
      - Go to 'Visit Dates' under Visit 1
        - Delete the data in the 'Actual visit date' field
          - **This must be blank for the BA and EQ-5D forms to be available**
  - Have the participant log into the iPad
  - Have the participant go to their study gmail account (the icon on the iPad dock at the bottom) and open the emails with the links to the questionnaires
  - There is a separate email for each questionnaire
  - Have the participant complete all questionnaires
    - For the "Baseline Asthma and Medical History - participant version" and "EQ-5D", the participant will need to log into the study website to do these
    - For all others, they will just click the link in the email
- Once all the questionnaires are complete, enter the 'Actual visit date' into 'Visit Dates' for Visit 1

Actual visit date	<input type="text" value="08-25-2014"/> <input type="button" value="Today"/> <input type="button" value="M-D-Y"/>
<small>The date of visit 1 must be entered for participant to access the Trial Website and diary reports.</small>	

- In the MICT-data REDCap project
  - Click 'Add/Edit Records' and choose the participant ID for this participant
  - Go to the 'Visit Dates' form under Visit 1
  - Complete the field for 'Actual visit date'
  - Set form as 'Complete'
  - Click 'Save'
  - **Note:** When a date for this field has been saved, the participant is automatically given access to the Trial website (and Morning and Evening

Reports) when logging in. If no date has been saved, the participant only has access to the Consent website when logging in.

- Complete all the study procedure up to the point of demonstrating the features of the Trial website
- PFT data must be entered to obtain the Temporary Asthma Action Plan and have it available on the iPad (**Click here to see [Study Coordinator REDCap Instructions for Visit 1 \(Clinic\)](#) section in this MOP.**)
  -
- Completely shut down and restart the participant's iPad
  - Hold down the Sleep/Wake button for several seconds.



- The iPad will prompt you to slide a button to power off the iPad. Follow the directions on the screen by sliding the button from the left side to the right to reboot the iPad.
- **If the iPad is frozen or stuck**, hold down both the Sleep/Wake button and the Home button. This will force the iPad to power down.



- The iPad screen will display the circle of dashes which indicates it is busy. Once the iPad has finished shutting down completely, the screen will go completely black.
- Once the iPad's screen is completely black, hold down the Sleep/Wake button for several seconds. This will allow you to restart the iPad.
- When the Apple logo appears in the middle of the screen, you can release the Sleep/Wake button. The iPad will restart shortly after the logo appears.
- This will reset any cookies that have been saved and allow the participant to access the Trial website by entering their user name and password
- The participant should now enter their user name and password and access the Trial website so that you can show them the Morning and Evening report (follow the instructions in section "iPad Review" (**Click here to see "[iPad Review](#)" section in this MOP. Click this link to view the guide: [Coordinator Instructions for Training Participants to use iPad at Visit 1.](#)**

#### 15.4. Is my Participant Using the Diskus Like They Should?

Go to the MICT-DC Summary REDCap project and under Reports, click on "Med and diary reporting summary".

OR

Go to MICT-data REDCap project and under Project Bookmarks, click on "Peak Flow report"

- Enter Nemours Username and password (MICTstudy2013) and you can see the counter number reported by your participant and what the expected counter number is based upon when the participant indicated they started a new diskus.

Participant ID:

Start date:  (mm/dd/yyyy)

End date:  (mm/dd/yyyy)

Note:

- Dose taken: ✓
- Dose not taken: ✗
- Diary card not submitted: blank
- 'Sum' is the total number of reports submitted
- 'Diskus Counter #' is the study Diskus counter number reported by the participant
- 'Expected Counter #' is the expected study Diskus counter number based on the number of days the participant has been taking the Diskus
- 'Started new Diskus' indicates when a new Diskus was started. 'M' means the new Diskus was started on the morning dose.

Sum	22	25			
Date	Morning Dose	Evening Dose	Diskus Counter #	Expected Counter #	Started New Diskus
2014-08-01	✓	✓			
2014-08-02	✓				M
2014-08-03	✓	✓	56	56	
2014-08-04	✓	✓			
2014-08-05		✓			
2014-08-06	✓	✓			
2014-08-07	✓	✓	48	48	
2014-08-08	✓	✓			
2014-08-09		✓			

### 15.5. What are my Participant's Peak Flow Values?

Go to the MICT-DC Summary REDCap project Under Reports, click on "Med and diary reporting summary".

OR

Go to MICT-data REDCap project and under Project Bookmarks, click on "Peak Flow report"

- Enter Nemours Username and password (MICTstudy2013) and you can see the counter number reported by your participant and what the expected counter number is based upon when the participant indicated they started a new diskus.

Participant ID:

Start date:  (mm/dd/yyyy)

End date:  (mm/dd/yyyy)

Date:

Temporary Asthma Action Plan

Personal best PEF:

65% of personal best PEF:

85% of personal best PEF:

You will see the 65% and 85% limits for both the Temporary Asthma Action Plan (used from V1 to V3) and the Asthma Study Asthma Action Plan (used from V3 to V6). The actual values will be green, yellow, or red to make it easy to view which zone a peak flow falls in.

Participant ID: JAX113a  
 Start date: 5/1/2014 (mm/dd/yyyy)  
 End date: 7/31/2014 (mm/dd/yyyy)

Date: 2014-03-20  
 Temporary Asthma Action Plan  
 Personal best PEF: 369  
 65% of personal best PEF: 240  
 85% of personal best PEF: 314

Date: 2014-05-18  
 Asthma Study Asthma Action Plan  
 Base mean PEF: 335  
 65% of baseline mean PEF: 218  
 85% of baseline mean PEF: 285

Date	Morning peak flow
2014-05-05	341
2014-05-06	330
2014-05-07	325
2014-05-08	342
2014-05-10	314
2014-05-11	341

### 15.6. How Much Albuterol is my Participant Using?

Go to the [MICT-diary cards](#) REDCap project

Under Reports, click on “Drug use for quick relief” and you can see all the values for MDI and nebulizer. If you use the find feature (ctr F) your participant ID will be highlighted and easier to see among all the others.

Participant ID of the patient. (participant_id)	Diary card date (mdc101)	# puffs per day by metered dose inhaler Enter "0" if no rescue medication was used. (dc106a)	# uses per day by nebulizer Enter "0" if no rescue medication was used. (dc106b)	Counter number on your inhaler (vent_doses_remain)
ORL106	2014-05-09	0	0	66
ORL106	2014-05-10			
ORL106	2014-05-11	0	0	60
ORL106	2014-05-12	2	0	56
ORL106	2014-05-13	2	0	52
ORL106	2014-05-14	2	0	52
ORL106	2014-05-15	0	0	50
ORL106	2014-05-16	2	0	48

### 15.7. Has my Participant had any Unscheduled Visits?

Go to the [MICT-diary cards](#) REDCap project

Under Reports, click on “Questions about urgent unscheduled medical attention” and you can see all the Evening Report questions and the participant responses. If you use the find feature (ctr F) your participant ID will be highlighted and easier to see among all the others. You will also have alerts sent to your email with these alerts but here you can see them all in one place.

An alternative to see all alerts on your participant:

Go to the [MICT-diary cards](#) REDCap project

- Under Project Bookmarks, click on “Alerts Summary”. Enter Nemours Username and password (MICTstudy2013) and you can see the all the alerts that you have been sent by email over the study duration for your participant.



## 15.8. How do I make Edits to my Participants Morning or Evening Reports?

Go to the MICT-diary cards REDCap project

Under Data Collection, click on “Add / Edit Records”. Then look down to “Data Search” and “Choose a field to search”. Select “record (Record) this is the primary key...”

**REDCap™**

Logged in as **kblake** | Log out

**My Projects**

- Project Home
- Project Setup
- Project status: **Production**

**Data Collection**

- Record Status Dashboard
- Add / Edit Records

Data Collection Instruments:

- Day
- Morning
- Evening
- Notes

**Applications**

- Data Export Tool
- Field Comment Log
- File Repository
- User Rights
- Graphical Data View & Stats
- Report Builder

**Project Bookmarks**

- MICT - data
- MICT - DC summary
- Med and diary reporting summary

**Reports**

- test
- Doses
- Diskus counter
- Peak flow
- Drug use for quick relief
- Peak flow - JAX102a
- New Diskus started in morning
- New Diskus started in evening

**Help & Information**

- Help & FAQ
- Video Tutorials
- Suggest a New Feature

If you are experiencing problems, please contact your REDCap administrator.

**Nemours.**

Nemours / Alfred I. duPont Hospital for Children  
Nemours Biomedical Research

**MICT - diary cards**

Actions: [Download PDF of instrument\(s\)](#)

**Day**

You may view an existing record/response by selecting it from one of the drop-down lists below. The records are separated into each drop-down list according to their status for this particular data collection instrument. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

Total records: 357

Incomplete Records (353)

Complete Records (4)

Enter a new or existing Record This is the primary key for this project. It is created using the participant ID and date for the submission.

[Show Unverified Records above](#)

**Data Search**

Choose a field to search (excludes multiple choice fields)

Search query

Begin typing to search the project data, then click an item in the list to navigate to that record.

✓ -- select search field --

- record (Record This is the primary key for this project. It is created using the participant ID and date for the submission.)
- participant\_id (Participant ID of the patient.)
- mdc101 (Diary card date)
- diskus\_days (Number of days old Diskus was in use. This field will b...)
- time\_am (Date/timestamp for submission of morning diary card.)
- peakflow1 (Morning peak flow - first measurement)
- peakflow2 (Morning peak flow - second measurement)
- peakflow3 (Morning peak flow - third measurement)
- dc102 (Morning peak flow. Highest of the 3 peak flow measurements.)
- dcm\_cv115bs (Specify reason you decided to temporarily stop taking t...)
- dcm\_cv115fs (Specify side effects)
- dcm\_cv115hs (Specify some other reason)
- time\_pm (Date/timestamp for submission of evening diary card.)
- doses\_remain (Counter number on your diskusPresented on diary report...)
- doses\_expect (Expected counter number on Diskus.This is based on the...)
- dce\_cv115bs (Specify reason you decided to temporarily stop taking t...)
- dce\_cv115fs (Specify side effects)
- dce\_cv115hs (Specify some other reason)
- dc106a (# puffs per day by metered dose inhaler Enter "0" if no res...)
- vent\_doses\_remain (Counter number on your inhaler)
- dc106b (# uses per day by nebulizer Enter "0" if no rescue medicati...)
- mdc110cs (Tell us about this event)
- mdc110ds (Tell us about this event)
- mdc110es (Tell us about this event)
- mdc110fs (Tell us about this event or illness)
- mdc125\_date (What date did this happen?)

The REDCap Consortium | Citing REDCap | Nemours Biomedical Research

REDCap Software - Version 5.10.0 - © 2014 Vanderbilt University

In the “Search Query” field start typing in the participant ID and date of interest in this format: orl131\_2014-05-23 (upper or lower case for orl/wil/jax/pns/phl is fine). You will see rows (15 rows) of dates you can choose from as you start to type in. If you only type in orl131\_2014-05, you will see dates from May 1 to May 15. This search box only holds 15 rows. Type in the complete date to get to the record you want.

**Data Search**

**Choose a field to search**  
(excludes multiple choice fields)

record (Record This is the primary key for this proj) ▾

**Search query**  
Begin typing to search the project data, then click an item in the list to navigate to that record.

orl131\_2014-05

- \***ORL131\_2014-05-01**" in Record This is the primary key for
- \***ORL131\_2014-05-02**" in Record This is the primary key for
- \***ORL131\_2014-05-03**" in Record This is the primary key for
- \***ORL131\_2014-05-04**" in Record This is the primary key for
- \***ORL131\_2014-05-05**" in Record This is the primary key for
- \***ORL131\_2014-05-06**" in Record This is the primary key for
- \***ORL131\_2014-05-07**" in Record This is the primary key for
- \***ORL131\_2014-05-08**" in Record This is the primary key for
- \***ORL131\_2014-05-09**" in Record This is the primary key for
- \***ORL131\_2014-05-10**" in Record This is the primary key for
- \***ORL131\_2014-05-11**" in Record This is the primary key for
- \***ORL131\_2014-05-12**" in Record This is the primary key for
- \***ORL131\_2014-05-13**" in Record This is the primary key for
- \***ORL131\_2014-05-14**" in Record This is the primary key for
- \***ORL131\_2014-05-15**" in Record This is the primary key for

In this example the date for ORL131\_2014-0508 was selected:

**Day**

Record This is the primary key for this project. It is created using the participant ID and date for the submission. ORL131\_2014-05-08 [Select other record](#)

Data Collection Instruments:

- ☒ Day
- ☐ Morning
- ☐ Evening
- ☐ Notes

**Applications**

- [Data Export Tool](#)
- [Field Comment Log](#)
- [File Repository](#)
- [User Rights](#)

Editing existing Record This is the primary key for this project. It is created using the participant ID and date for the submission. ORL131\_2014-05-08

Record This is the primary key for this project. It is created using the participant ID and date for the submission. ORL131\_2014-05-08

Participant ID of the patient.

Diary card date   Y-M-D

Number of days old Diskus was in use. This field will be completed if a new Diskus was started in the morning or evening..

This field is not automatically updated if the start of a new Diskus is entered by hand.  Computer code will complete this field.

**Form Status**

Select "morning" or "evening" (on the left) for the report you need to correct. To correct an entry, make the change that is needed. Then click on the little callout icon (like in comics for a character speaking).

This was a phone contact with my doctor's office about my asthma. ☐ Yes ☒ No [reset](#)

This was a clinic visit to the study site about my asthma ☐ Yes ☒ No [reset](#)

This was a visit to my doctor's office about my asthma ☐ Yes ☒ No [reset](#)

This was an emergency department visit ☐ Yes ☒ No [reset](#)

In the Comments box, write the justification for making the change (e.g., spoke the parent and the child did not go to the ED"). You don't need to sign your name because you will see that you are the user. Your note will now show up under the comments for anyone else who logs into that record. The "H" in the circle will show you the history of all the changes to that field.

**Field Comment Log**

This pop-up displays all the field comments for the record and field specified below. Users with access to data entry forms may leave one or more comments on any field on a data collection instrument, after which the balloon icon will stay lit up to signify that comments exist for that field for this record. All field comments for all records/fields can also be viewed, keyword searched, and filtered on the [Field Comment Log](#) page in this project.

Record This is the primary key for this project. It is created using the participant ID and date for the submission.: [ORL131\\_2014-05-08](#)

Field: mdc110c ("This was an emergency department visit")

Date/Time	User	Comments
05/27/2014 5:23pm	kblake	

Comment Cancel

Also: **[Click here to see “Correcting Entry when Diskus Started but not Indicated on Diary Report” section in this MOP.](#)**

### 15.9. Has my Participant Completed Enough Morning and Evening Reports to Qualify for Visit 3?

Go to the [MICT-data](#) REDCap project

Under Project Bookmarks, click on “Med and diary reporting summary”. Enter Nemours Username and password (MICTstudy2013). You will need to enter the participant ID (use caps for letters) and start and end date. Make sure you use the correct format.

Remember that in order to qualify for Visit 3, the participant must have completed 10 of the last 14 days of diary entries (at least one Morning or Evening entry on 10 of the 14 days).

### 15.10. Has my Participant Taken Advair 250/50 on Enough Days to Qualify for Visit 3?

Go to the [MICT-data](#) REDCap project

Under Project Bookmarks, click on “Med and diary reporting summary”. Enter Nemours Username and password (MICTstudy2013). You will need to enter the participant ID (use caps for letters) and start and end date. Make sure you use the correct format.

Remember that in order to qualify for Visit 3, the participant must have taken at least 1 dose per day for 21 of the last 28 days.

### 15.11. How do I determine the mean PEF at Visit 3 for the Study Asthma Action Plan?

Go to the [MICT-data](#) REDCap project

Under Project Bookmarks, click on “Calculate mean PEF (for 14 days)”. Enter Nemours Username and password (MICTstudy2013). You will need to enter the participant ID (use caps for letters).

TIP:

Please note that if the current day (the day of Visit 3) PEF is needed to have 10 PEF values from the last 14 days to meet the randomization eligibility criteria then the calculation from that link will not include the current day. This is because the data updates at 4AM each day. Therefore you will need to copy and paste the 9 available days into Excel, then get the day's current PEF and add it to Excel.

To get the current day's PEF:

Go to the [MICT-diary cards](#) REDCap project

Under Reports, click on "Peak flow" and scroll to the participant and today's date. You can also select "Ctrl F" and search in this format "JAX102\_2014-01-08" [year-month-day].

Have Excel calculate the mean PEF for the 10 of the last 14 days of PEF data.

### 15.12. What are all the Alerts I have Received on my Participant?

Go to the [MICT-data](#) REDCap project

Under Project Bookmarks, click on 'MICT-alerts', then under Project Bookmarks, click on "Alerts summary". Enter the Participant ID and the date range you are interested in.

Participant ID:

Start date:  (mm/dd/yyyy)

End date:  (mm/dd/yyyy)

NOTE: Click 'Submit' to refresh the report after adding 'Study staff notes' to the MICT-alerts REDCap project.

NOTE: The column with content of the email messages appears here.

Date	Type of alert	Content
------	---------------	---------

You will see all the alerts and from what type of entry it was generated from (eg. screening form, morning or evening report, etc).

Participant ID:

Start date:  (mm/dd/yyyy)

End date:  (mm/dd/yyyy)

NOTE: Click 'Submit' to refresh the report after adding 'Study staff notes' to the MICT-alerts REDCap project.

NOTE: The column with content of the email messages contains the original alert message. This content is not updated. Changes made in the original message will not appear here.

Date	Type of alert	Content of email message	Study staff notes	Record ID
2014-06-30	upcoming visit	Participant ORL106a has a visit scheduled for Visit1 on 2014-07-07 14:15. If this visit has been rescheduled, please update the MICT-data REDCap project.		<a href="#">ORL106a_1404117902</a>
2014-07-03	screening form	1. This child may be taking too much medication. The answers to the questionnaire indicate the child is using both a combination medication and an additional corticosteroid inhaler. 2. The child and parent/guardian are not accessible by telephone.		<a href="#">ORL106a_1404439301</a>
2014-07-06	screening form	1. The child and parent/guardian are not accessible by telephone.		<a href="#">ORL106a_1404694256</a>
2014-07-07	evening card	1. Participant ORL106a started new Diskus with this dose, and old Diskus was in use for days.		<a href="#">ORL106a_1404770532</a>

To see if you or another coordinator resolved the alert (if it needs to be resolved) (see the alert on 7/6/2014 about not being accessible by telephone), you will need to go to the original data form (e.g. screening form shown below) and click the balloon icon which will be yellow (vs. clear) if an entry has been made:



\* must provide value

Are you and your parent/guardian accessible by telephone? ☒ Yes ☐ No

\* must provide value

Do you anticipate moving in the next 6 months? ☐ Yes ☐ No

You will be able to see who made the correction and what the resolution was (just looking at an entry (e.g. kblake on 8/18/2014) does not generate a new entry for this item):

	Date/Time	User	Comments
	07/06/2014 8:53pm	alprice	mom is available by phone selected wrong answer
	08/18/2014 1:45pm	kblake	<input type="text"/>
<input type="button" value="Comment"/> <input type="button" value="Cancel"/>			

Note that the “Study staff notes” on the right are NOT the notes that you may have entered when you corrected the alert message on a Morning or Evening Report or study form. You will need to go to the actual form (screening or morning or evening report) of the date of interest to view the comments. However, once you have edited the diary report or questionnaire as needed, you can return to this form to enter “Resolved” in the “Study Staff notes”. To enter “resolved”, click on the link under the column “Record ID”. Doing this step will then allow you to quickly see which alerts have been resolved as the participant progresses through the study.

### 15.12.1. What alerts do I need to act on?

#### 15.12.1.1. Medical Issues

Medical issues and adverse events need to be acted upon by the study coordinator immediately. See [Adverse Events](#) section in this MOP.

#### When to Assess

- Adverse events are assessed on a continual basis through the study from data collected on the Morning/Evening Reports, FaceTime appointments, onsite appointments, etc.

(Click here to see [Adverse Events](#) section in this MOP).

Medication Adherence: The parent should be notified if

Adherence is below 70% consistently (over several days – use your judgment)

If study medication has been missed for more than 14 days in a row (for either morning or evening doses (this would indicate that adherence is <50%))

Missed Morning and Evening Reports:

Review at the next FaceTime visit. If morning reports are missed, remind the participant that we need their PEF in order to have their asthma action plan pop up on the iPad to help prevent an asthma exacerbation. If evening reports are missed, remind the participant that this is the place they let us know about any medical events that have happened so that we can help with management right away.

### 15.13. How can I find out if Heights have changed on my Participant?

Go to the MICT-diary cards REDCap project

Under Reports, click on “Height summary”. Use “Ctrl F” to search by Participant ID and you can see all the heights recorded in REDCap.

### 15.14. How can Another Coordinator Cover Alerts when I am Out of Town?

Go to the MICT-data REDCap project. You will need to add the email address of the coordinator who will be covering to each of your study participants “Study Information” form. This may be tedious but it is the only way.

Select your first active participant and go to the “Study Information” form:

Participant ID <b>ORL131</b> <small>K</small> (Arm)				
Data Collection Instrument	Ongoing (1)	Screening (2)	Visit1 (3)	Visit2 virtua (4)
Participant ID				
Patient Screening Log				
Study Information				
Participant Information				
Signed Consent				

Once the form is open, scroll down to where you will add the covering study coordinator:

**Additional email address for alert messages.**

Complete this field when a clinical coordinator from another site will be covering this participant. Remove the email address when alert messages should no longer be sent to it.

When adding more than one email address, type a comma between the addresses.

The email address(es) in this field will be included when alerts about this participant are sent.

[reset](#)

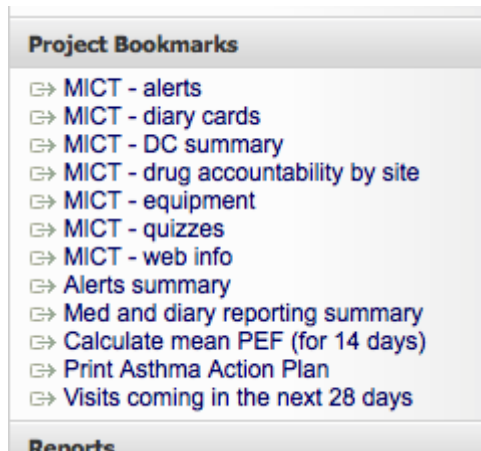
When you have returned, you can delete the covering study coordinator(s) email address.

### 15.15. What Study Visits do I have Coming Up in the Next 28 Days?

Go to the MICT-data REDCap project. There are 2 ways to view your upcoming appointments. Viewing your upcoming appointments in REDCap is important because if you have changed the date between you and the participant, but have not updated REDCap to reflect the correct date, then the forms and questionnaires will be sent out either too soon (if the the actual visit date is LATER than in REDCap) OR won't be sent in time for the visit if the actual visit date is SOONER than in REDCap).

#### Method 1:

Under Project Bookmarks, click on “Visits coming in the next 28 days”.



Type in your Nemours user name and the password “MICTstudy2013”.

Select your site.

These are your visits in the next 28 days. This will give you time to adjust REDCap to send out the forms at the correct date for your visit if needed.



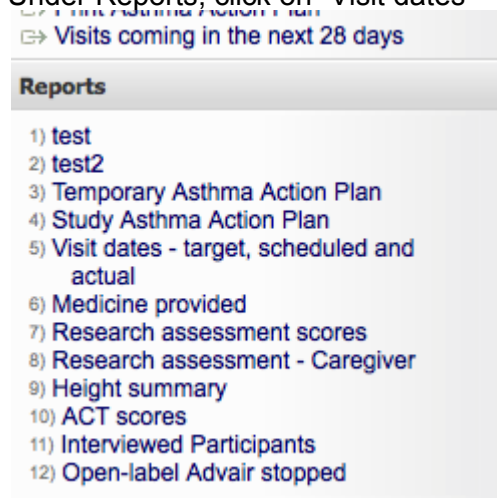
Participant ID	Event	Scheduled Date
<a href="#">ORL106a</a>	Screening	2014-07-07 14:30
<a href="#">ORL106a</a>	Visit1	2014-07-07 14:15
<a href="#">ORL117</a>	Visit5-virtual	2014-07-07 10:30
<a href="#">ORL117</a>	Visit6-virtual	2014-07-28 14:00
<a href="#">ORL117</a>	Visit6-clinic	2014-07-31 09:00
<a href="#">ORL131</a>	Visit6-virtual	2014-07-28 10:01
<a href="#">ORL136</a>	Visit5-virtual	2014-07-21 14:00

Please select study site:

☐ JAX  
☐ ORL  
☐ WIL  
☐ PNS

## Method 2:

Under Reports, click on “Visit dates – target, scheduled and actual”.

















Use “Ctrl F” to open the “find” window and type in your participant ID (for example ORL117)

Participant ID (participant_id)	Event Name (redcap_event_name)	Participant's last name (mpi107c)	Participant's first name (mpi107a)	Other name(s) the participant uses (if applicable) (mpi107d)	Target date (date_target)	Scheduled date and time (date_sch)	Actual visit date (date_visit)	Nemours study site (study_site)	Arm of study (arm)
<a href="#">ORL106a</a>	Visit2-virtual				2014-08-04				
<a href="#">ORL106a</a>	Visit3-virtual				2014-09-01				
<a href="#">ORL117</a>	Ongoing	Ayson	Travis					ORL (2)	MICT (1)
<a href="#">ORL117</a>	Screening					2014-01-29 15:00	2014-01-29		
<a href="#">ORL117</a>	Visit1				2014-03-17	2014-03-17 14:00	2014-03-17		
<a href="#">ORL117</a>	Visit2-virtual				2014-04-14	2014-04-15 14:30	2014-04-15		
<a href="#">ORL117</a>	Visit3-virtual				2014-05-12	2014-05-15 15:00	2014-05-14		
<a href="#">ORL117</a>	Visit4-virtual				2014-06-05	2014-06-10 17:16	2014-06-10		
<a href="#">ORL117</a>	Visit5-virtual				2014-06-26	2014-07-07 10:30			
<a href="#">ORL117</a>	Visit6-virtual				2014-08-07	2014-07-28 14:00			
<a href="#">ORL117</a>	Visit6-clinic				2014-08-07	2014-07-31 09:00			
<a href="#">ORL117</a>	Unscheduled1								

Under “Event Name”, you will see all the visit types such as Screening, Visit 1, etc. Double check that the dates shown here are what you have in your outlook calendar. If the dates in

REDCap are incorrect please put the correct date in the visit dates field for your participant shown below.

Data Collection Instrument	Ongoing (1)	Screening (2)	Visit1 (3)	Visit2- virtual (4)	Visit3- virtual (5)	Visit4- virtual (6)	Visit5- virtual (7)	Visit6- virtual (8)	Visit6- clinic (9)
Participant ID									
Patient Screening Log									
Study Information									
Participant Information									
Signed Consent									
Drug Accountability Log									
Treatment Termination									
Visit Dates									

### 15.16. How to Use CTPayer Card for Online or Phone Purchases?

You can cut and paste the below to email to the participant:

When making a purchase online or over the phone, you must enter the billing address associated with your card. The billing address is located on the card carrier that came with your card. When making a purchase for an amount greater than your available balance, instruct the merchant to charge an amount equal to your available balance and then pay the remainder using another form of payment.

**Name for the Card should be listed:** Nemours MICT

**The billing address listed on the card insert:** 807 Children's Way Jacksonville, FL 32207

Enter your **shipping name** and address during the check out process.

## 16. MICT Trac Site (Helpful Tools and Reference Pages [wiki pages])

### Links to administrative web pages

There are links to these web pages in various places in REDCap. Many are in the left sidebar of the project MICT-data. Some are within forms where the link would be used in the work flow.

Each staff member has a single login name and password for these web pages. Contact Suzanne or Chris if you need help remembering your login name or password.c

Username: Nemours login

Password: MICTstudy2013

You'll enter the username and password twice, then you will then to enter the Participant ID.

### LIVE web pages

Send email message to parent's email address with info about next phone call and consenting phone appointment date.

[https://apps.nemoursresearch.org/mict/admin/about\\_study\\_email.php](https://apps.nemoursresearch.org/mict/admin/about_study_email.php)

List the visits for all participants that are scheduled in the next 28 days. This has links to each record in REDCap. This link is hard coded with a REDCap version number. REDCap currently converts the URL to the most recent REDCap version. When there are major upgrades to REDCap, this link should be checked to see if it is still being redirected to the correct url.

[https://apps.nemoursresearch.org/mict/admin/upcoming\\_visits.php](https://apps.nemoursresearch.org/mict/admin/upcoming_visits.php)

Generates a report summarizing diary card submissions, study meds and Diskus counts taken for custom time frames for a single participant.

[https://apps.nemoursresearch.org/mict/admin/diary\\_submission.php](https://apps.nemoursresearch.org/mict/admin/diary_submission.php)

Generates a report summarizing alerts for custom time frames for a single participant

<https://apps.nemoursresearch.org/mict/admin/alerts.php>

Generates a report summarizing peak flow measurements for custom time frames for a single participant.

[https://apps.nemoursresearch.org/mict/admin/peakflow\\_report.php](https://apps.nemoursresearch.org/mict/admin/peakflow_report.php)

Calculates the Baseline PEF for the past 14 days for a single participant.

<https://apps.nemoursresearch.org/mict/admin/baselinePEF.php>

Displays the Asthma Action Plan for a single participant. (This can be printed.) The Temporary Asthma Action Plan is displayed if the participant has completed visit 1 and not completed visit 3. The Asthma Study-Asthma Action Plan is displayed if the participant has completed visit 3.

<https://apps.nemoursresearch.org/mict/admin/actionPlan.php>

### **TEST web pages**

Send email message to parent's email address with info about next phone call and consenting phone appointment date.

[https://www.nemoursresearch.org/mict/admin/about\\_study\\_email.php](https://www.nemoursresearch.org/mict/admin/about_study_email.php)

List the visits for all participants that are scheduled in the next 28 days. This has links to each record in REDCap. REDCap currently converts the URL to the most recent REDCap version. When there are major upgrades to REDCap, this link should be checked to see if it is still being redirected to the correct url.

[https://www.nemoursresearch.org/mict/admin/upcoming\\_visits.php](https://www.nemoursresearch.org/mict/admin/upcoming_visits.php)

Generates a report summarizing diary card submissions, study meds and Diskus counts taken for custom time frames for a single participant.

[https://www.nemoursresearch.org/mict/admin/diary\\_submission.php](https://www.nemoursresearch.org/mict/admin/diary_submission.php)

Generates a report summarizing alerts for custom time frames for a single participant

<https://www.nemoursresearch.org/mict/admin/alerts.php>

Generates a report summarizing peak flow measurements for custom time frames for a single participant.

[https://www.nemoursresearch.org/mict/admin/peakflow\\_report.php](https://www.nemoursresearch.org/mict/admin/peakflow_report.php)

Calculates the Baseline PEF for the past 14 days for a single participant.

<https://www.nemoursresearch.org/mict/admin/baselinePEF.php>

Displays the Asthma Action Plan for a single participant. (This can be printed.) The Temporary Asthma Action Plan is displayed if the participant has completed visit 1 and not completed visit 3. The Asthma Study-Asthma Action Plan is displayed if the participant has completed visit 3.  
<https://www.nemoursresearch.org/mict/admin/actionPlan.php>

# THE END!